The Experiences of Low-Risk and HIV Anxious Gay Men who are using HIV Pre-Exposure Prophylaxis (PrEP): A Qualitative Study

C. P. McCormack

A thesis submitted for the degree of Doctorate in Clinical Psychology (DClinPsych)

School of Health & Social Care

University of Essex

September 2021

ACKNOWELDGEMENTS

I consider this thesis to be a product of not only the research that I have conducted but of my journey towards becoming a Clinical Psychologist. As such, there are many people who have helped me along the way, who I am indebted to. I want to take this opportunity to offer my sincere thanks. That said, there are a few people that deserve a special mention for their contribution to this thesis.

Firstly, I would like to offer my thanks to the participants who kindly offered to participate. Without their voices, there would be no story to tell. I hope that my work represents your experiences fairly and respectfully.

I would also like to acknowledge the superb supervision I have received from my supervisors: Professor Gill Green and Dr Richard Pratt. Gill and Richard have offered dedicated support throughout this project and they have successfully steered me to submission.

Finally, I would like to thank my friends and family for their support during this process.

TABLE OF CONTENTS

STATEMENT OF TERMS

Throughout this thesis the following abbreviations have been adopted:

AIDS – Acquired Immune Deficiency Virus

CAI – Condomless Anal Intercourse

CBT – Cognitive Behavioural Therapy

EBD – Event Based Dosing

HIV – Human Immunodeficiency Virus

OCD – Obsessive Compulsive Disorder

PrEP – Pre-Exposure Prophylaxis

PEP – Post Exposure Prophylaxis

STI – Sexually Transmitted Infections

There are various terms that are commonly used to describe sex between men. In recent years, men who have sex with men (MSM) is widely used within public health discourse. However, this purportedly neutral term is problematic as it obscures the social and psychological dimensions of sexuality and may undermine the self-labelling of gay and bisexual men. These dimensions are crucial in the current study and therefore this thesis will adopt the term gay and bisexual men (GBM) in place of MSM.

RESEARCH SUMMARY

Aims: To explore the experiences of low-risk, HIV anxious gay and bisexual men (GBM) who use HIV Pre-Exposure Prophylaxis (PrEP) and the impact PrEP use has on their sexual behaviour and experience of anxiety.

Background: PrEP has demonstrated significant protection against HIV infection among GBM who are high-risk and is becoming increasingly popular. Anecdotal reports suggest that low-risk, HIV anxious GBM are using PrEP. HIV anxiety in GBM is a poorly understood phenomenon that is usually conceptualised within cognitive-behavioural models. This may neglect the impact of minority status and the specific psychosocial processes associated with this, such an internalised homophobia. PrEP use is associated with less worry and improved sexual functioning and it is unknown whether these benefits will be realised among PrEP-using, low-risk GBM who are HIV anxious.

Methodology: Qualitative methodology was employed within an interpretivist paradigm. 10 gay men were recruited from sexual health clinics in central London. Participants were included in the current study through either historically or currently meeting diagnostic criteria for Illness Anxiety Disorder, were considered low risk for acquiring HIV infection and had been using PrEP for at least 3 months. In-depth semi-structed interviews were conducted. Data was analysed by means of thematic analysis.

Results: Twenty-two themes, and accompanying subthemes, were extracted from participants' data. Participants experienced adversity in adjusting to their sexuality. These experiences may have led to internalised homophobia that impacted perception of sexuality and contributed to development of HIV anxiety. HIV anxiety was characterised by various cognitive and behaviour manifestations, as well as shame. PrEP use was initiated to mitigate anxiety symptoms and improve psychological and psychosexual functioning. All

participants experienced less anxiety and improved psychosexual functioning after starting PrEP.

Conclusions: HIV anxiety in GBM may be a consequence of psychosocial processes associated with minority stress. The experience of HIV anxiety in GBM is not adequately captured within current diagnostic classifications or psychological theories and models of anxiety disorders. PrEP use in this group may be better conceptualised as a community adaptive coping strategy rather than a safety behaviour. PrEP therefore may be a useful intervention for GBM who are HIV-anxious.

CHAPTER ONE: INTRODUCTION

Chapter Overview

The history of the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) is one of the most fascinating stories, that not only tells of human suffering but also of hope, human perseverance, and the might of science. There have been many advances, such as the isolation of the causative virus (i.e., HIV), development of highly active anti-retroviral therapy and challenging societal prejudice: HIV has been transformed from a terminal illness to a long-term health term condition, which is almost always manageable.

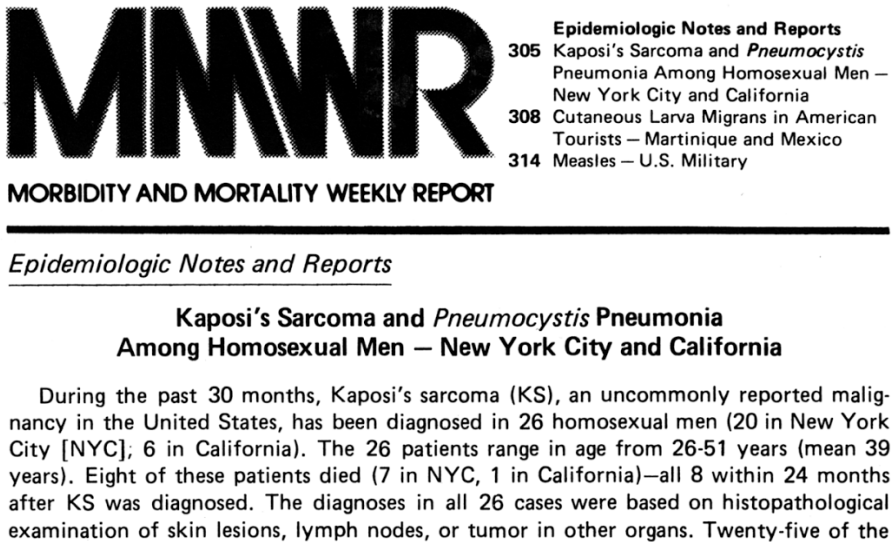
Another great feat in the story of HIV and AIDS is the development of and access to pre-exposure prophylaxis (PrEP), which has been hailed as a 'game changer' (Nwokolo et al., 2017). Along with a combination of other HIV prevention strategies, PrEP has already turned the tide in the number of new infections among GBM in the UK and is touted to play a key role in bringing an end to this devastating epidemic. However, HIV and AIDS has impacted GBM across the decades, which has led some in this population to experience excessive anxiety relating to HIV, irrespective of their sexual behaviours. This introduction weaves together the story of HIV and AIDS, PrEP and 'HIV anxiety' among GBM, to frame the empirical study.

Part I: The Early Years & HIV Overview

A New Gay Disease?

AIDS was first described as a clinical entity in 1981 (CDC, 1981; Freidman-Kien, 1981). Initial reports centred on an unusual increase in the incidence of Kaposi sarcoma (KS) and *Pneumocystis* pneumonia (PCP) among GBM in New York and California (see figures 1&2), diseases that were considered rare at the time. Despite these diseases being

occasionally observed in specific populations (e.g., KS in older men from the Mediterranean or PCP in patients with leukaemia after intensive chemotherapy), the occurrence of these diseases as indicators for severe immunodeficiency had not been observed previously in otherwise young healthy adults (CDC, 1981).



MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

Epidemiologic Notes and Reports

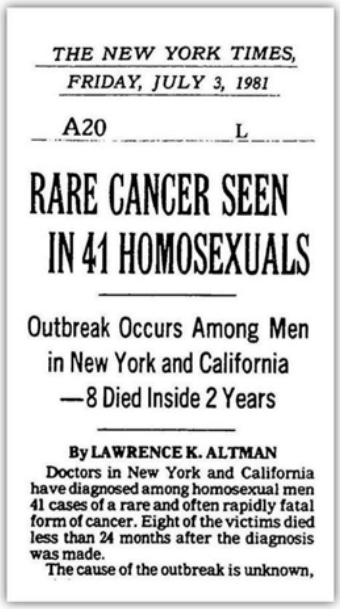
Epidemiologic Notes and Reports

Kaposi's Sarcoma and *Pneumocystis* Pneumonia Among Homosexual Men – New York City and California

During the past 30 months, Kaposi's sarcoma (KS), an uncommonly reported malignancy in the United States, has been diagnosed in 26 homosexual men (20 in New York City [NYC], 6 in California). The 26 patients range in age from 26-51 years (mean 39 years). Eight of these patients died (7 in NYC, 1 in California)—all 8 within 24 months after KS was diagnosed. The diagnoses in all 26 cases were based on histopathological examination of skin lesions, lymph nodes, or tumor in other organs. Twenty-five of the

Figure 1: Extract from Morbidity and Mortality Weekly Report, 1981: 305

Because the initially affected population was GBM, the disease, as well as those with the disease, were highly stigmatised (Altman, 1981) (see figure 2). The media referred to the syndrome as 'GRID', or gay-related immune deficiency (New York Times, 1982). In the early 1980s, the term 'gay plague' was also widely used, as well as similar terms for the associated AIDS-defining clinical conditions, such as "gay cancer" (see figure 3) for KS and "gay pneumonia" for PCP.



THE NEW YORK TIMES,
FRIDAY, JULY 3, 1981

A20 L

RARE CANCER SEEN IN 41 HOMOSEXUALS

Outbreak Occurs Among Men in New York and California —8 Died Inside 2 Years

By LAWRENCE K. ALTMAN

Doctors in New York and California have diagnosed among homosexual men 41 cases of a rare and often rapidly fatal form of cancer. Eight of the victims died less than 24 months after the diagnosis was made.

The cause of the outbreak is unknown,

Figure 2: Extract from The New York Times, 1981: "Rare cancer seen in 41 homosexuals"

Figure 3: First AIDS poster (Gay Cancer) by Bobbi Campbell in Castro's Star Pharmacy window, photo credit: Rink.

Initial understanding of the syndrome derived from the work of Selma Ditrz, who worked as Assistant Director of Public Health in San Francisco. Ditrz traced GBM who had been diagnosed with KS and interviewed them regarding their sexual practices and contacts. Consequently, she appeared to discover that the cases were connected by sexual contact. In

turn, this finding suggested that a transmittable pathogen may be responsible for AIDS, and therefore research intensified on exploring this hypothesis (Loewenberg, 2008).

As is commonplace in times of fear and uncertainty, scapegoats serve to assist people in directing their anger or frustration at otherwise incomprehensible circumstances, with AIDS being no exception to this. Many of those interviewed by Ditrz reported having sexual contact with a Canadian air steward named Gaetan Dugas. This led rise the so-called ‘patient zero’ theory (McKay, 2014): the assertion that Dugas was personally responsible for the propagation of AIDS across northern America. An epidemiological study (Auerbach et al., 1984) detailing a cluster of GBM with AIDS being linked, made a typo, which accelerated the traction that the ‘patient zero’ theory was gaining. Specifically, the authors had initially labelled Dugas in the study as ‘057’ but replaced this with ‘O’ (denoting ‘outside’, referring to the fact he did not reside in either New York City or San Francisco). A mistake in the study transcript led to ‘0’ being published instead of the intended ‘O’ (see figure 4) (Johnson, 2019). Nevertheless, the study did propose that Dugas may have infected some of the other ‘AIDS patients’.

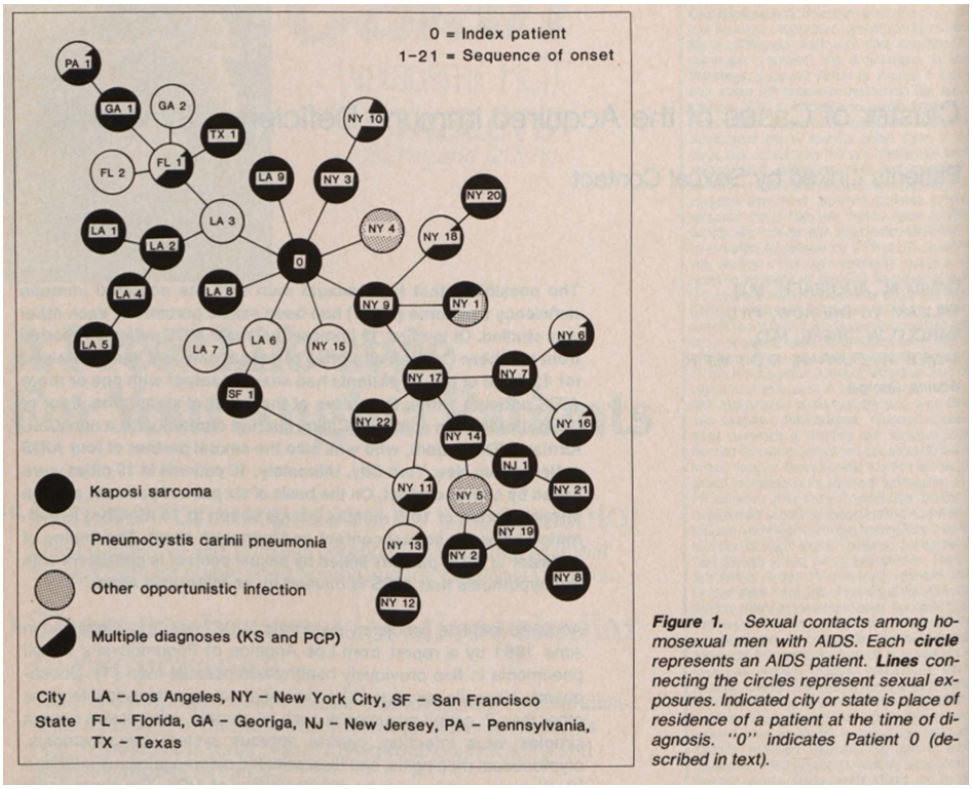


Figure 1. *Sexual contacts among homosexual men with AIDS. Each* ***circle*** *represents an AIDS patient.* ***Lines*** *connecting the circles represent sexual exposures. Indicated city or state is place of residence of a patient at the time of diagnosis. ''0'' indicates Patient 0 (described in text).*

Figure 4: Extract from Auerback et al (1984) study linking 40 AIDS patients by sexual contact. In the above graphic, Dugas is represented by the circle labelled 0, instead of O

Despite condemnation from public health officials, Dugas continued to be sexually active after he was diagnosed with KS. Consequently, there were discussions around legally forcing him to abstain from sex to cease the spread of AIDS, which as suggested by Jaspal and Bayley (2020), set a very dark precedent in the gay community. It is now widely accepted that the ‘patient zero’ theory was both inaccurate and damaging to the gay community (McKay, 2014) and perpetuated the stigmatization of GBM and those infected. It has since been proven that HIV arrived in northern America many years before Dugan was active (Worobey et al., 2016).

Figure 5: Photograph of Gaetan Dugas (1953-1984), photo credit: Fadoo Productions

A more likely propagator of AIDS was the gay bathhouses in which patrons at the time were reported to be having condomless anal intercourse (CAI) with multiple partners in a single visit. It is undisputed that this led to an exponential increase in cases in the US and Europe, where bathhouses and saunas were central features of gay communities (Woods et al., 2010). When it became increasingly clear that sexual behaviour was implicated in the spread of AIDS, there were calls from those in the gay community who were becoming increasingly worried about the impact AIDS, as well as public health officials, for the bathhouses to be closed (see figure 6).

Ban 'bad' sex, 10 baths told

By RUBEN ROSARIO and STUART MARQUES
Daily News Staff Writers

A gay bathhouse and a popular swinger's hangout are among 10 establishments warned by city officials to ban "dangerous sex" or be put out of business, the Daily News has learned.

Koch administration sources identified the businesses as the St. Mark's Baths in Greenwich Village and Pla-

Plato's says admission is $85 couple on the first visit and $55 subsequent trips. Unescorted men admitted Sunday, Monday and T day nights at $45 each and unescc women are admitted free. Thre the club's owners were sentence eight years in jail in 1981 for s ming $2.3 million in profits fron club.

Deadline for club owners

The owners of all the clubs

Figure 6: The New York Daily News, 10 November 1985, covered the city's edict against establishments permitting "dangerous sex"

However, the bathhouses were more than just a sexual meeting place; they were symbolic of the hard-fought civil rights for GBM (McKusick, Horstman, & Coates, 1985),

and therefore many in the community refused to co-operate with the proposed closures, despite the documented dangers (see figure 7). Although some were closed briefly, ultimately, they could continue to operate if they displayed posters highlighting the dangers of having sex without a condom (Raspal & Bayley, 2020). Despite attendance falling during this period, bathhouses continued to provide a key role in the transmission of new infections (Berube, 2003).

Figure 7: Protest at City Hall, San Francisco, against the closing of gay bathhouses to prevent the spread of HIV/AIDS, 15 October 1984, photo credit: Arthur Frisch/The Chronicles

A Global Epidemic

Although initially AIDS was exclusively observed in GBM, cases in non-GBM populations started to appear. Cases were emerging in those with haemophilia (CDC, 1982), people who were injecting drugs, such as heroin, and Haitian immigrants (CDC, 1982). This led to researchers briefly referring to AIDS as the '4H disease' (Cohen, 2006). In 1983, doctors in Kinshasa, Zaire (now known as the Democratic Republic of the Congo), reported a surge of opportunistic infections in the general population. This prompted US-based researchers to travel to Zaire and investigate. They concluded that the disease was being

transmitted through heterosexual sex. The World Health Organisation (WHO) held its first meeting in November 1983 to assess the global AIDS situation and begin international surveillance (WHO, 1984). At this meeting, it became apparent that cases of AIDS were increasing rapidly and whilst European countries, such as the UK, had similar epidemiological patterns as observed in the US (e.g., mostly affecting GBM), other countries, such as those in equatorial Africa and the Caribbean, were showing emerging patterns of infection in the general population. This represented a shattering realisation around the world: HIV was not isolated to only GBM, or other discrete groups deemed to be at risk instead, it presented the beginnings of one of the world's worst health disasters.

HIV: The Causative Agent

Initially, scientists hypothesised lifestyle and behavioural factors associated with homosexuality to be causally related to the development of AIDS. Postulated mechanisms included the use of amyl nitrate, which is an inhaled form of nitrates used by GBM during sex as a muscle relaxant (Durack, 1981). This served to further perpetuate the emerging stigma. However, in 1983 HIV was first isolated from the lymph node of gay man (Barre-Sinoussi et al., 1983; Gallo et al., 1983) and in 1984, HIV was the confirmed causative agent of AIDS (Gallo et al., 1984; Montagnier et al., 1984).

The Pathogenesis of HIV Infection

HIV is a retrovirus and belongs to the *Retroviridae* family and genus *Lentivirus* (Sabin and Lungren, 2013). It causes AIDS by interacting with many different cells in the human body and escaping the host immune response against it. HIV is transmitted through three main routes: sexual transmission, parenterally, and mother-to-child transmission (Shaw and Hunter, 2012). The sequence occurring in infection involves an interaction of HIV not only with CD4+ lymphocyte on cells but also with several other cellular receptors. Subsequently, virus-cell fusion and HIV entry occur. Following virus infection, a variety of

intracellular mechanisms determine the relative expression of viral regulatory and accessory genes leading to productive or latent infection. This leads to ongoing replication of the HIV virus in the body and depletion of host cells.

Thus, HIV progressively destroys CD4+ lymphocytes. These lymphocytes are crucial in co-ordinating the body's response against foreign cells, infectious organisms, and cancer. Therefore, once HIV destroys enough CD4+ lymphocytes, infected individuals become susceptible to attack by multiple infectious organisms. The graph below (see Figure 8) shows the trajectory of disease progression, in the absence of effective anti-retroviral treatment.

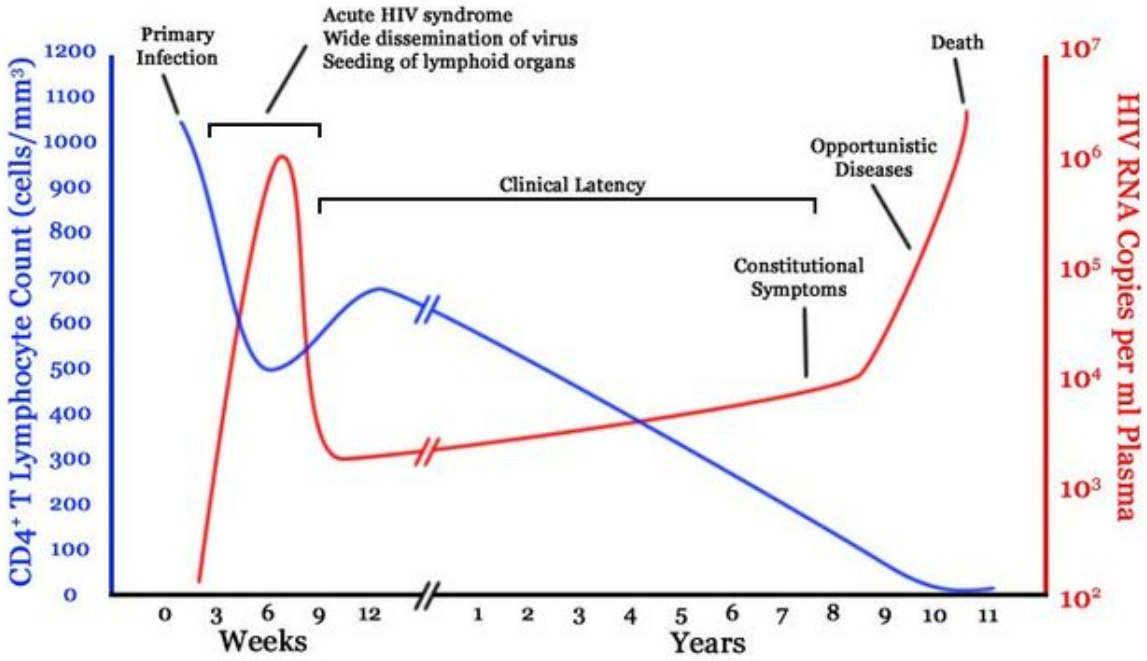


Figure 8: Natural history of HIV infection

Sexual Transmission

Sexual transmission is by far the most common mode of transmission. The probability of an individual becoming infected via sexual contact depends on the likelihood of them having CAI with an infected partner; therefore, sexual behaviour patterns and local prevalence of HIV are critical in determining risk. The chances of an individual becoming infected with HIV during a single sexual contact varies enormously (Mastro & de Vincenzi, 1996). Male to female penile-vaginal transmission appears to be 2-3 times more efficient than

female to male transmission (de Vincenzi, 1994; Nicolosi et al., 1994). Receptive sexual intercourse is riskier than both insertive anal intercourse and vaginal intercourse, which is why infection between GBM is relatively more likely (Caceres & van Griensen, 1994). Transmission because of oral sex has been reported; however, this mode of sexual transmission is thought to be much less risky than vaginal or anal penetrative sex (Mastro & de Vincenzi, 1996).

Another critical determinant of transmission is how infectious the infected partner is. Specifically, higher viral loads (i.e., the quantity of HIV viremia in the blood) at the advanced stage of the disease increases the probability of transmission; however, it is at the initial stage of the infection (e.g., seroconversion) that an individual has the greatest quantity of HIV viremia in sexual fluids and are therefore most infectious (Leynaert et al., 1998).

Determining the impact of an individual's treatment status (i.e., whether they were taking effective antiretroviral therapy at the time of intercourse) on transmission has been researched extensively in the last decade. The first randomised control trial (the HPTN 052 trial; Cohen et al., 2011) into the risk of transmission in this context, determined that in heterosexual couples the risk of transmission was reduced by 96% in those who were taking treatment, compared to those who were in the delayed arm. Subsequent follow up of those enrolled in the HPTN 052 trial, after which all participants had started treatment, showed that HIV-negative partners continued to remain seronegative. Despite encouraging data, only 2% of the couples were GBM (Cohen et al., 2016) and therefore results could not be generalised to this population, given the relative increased risk of receptive anal intercourse.

This led to the PARTNER study (PARTNER1; Rodger et al., 2016), which aimed to evaluate risk of transmission in the context of the HIV-positive partner taking effective treatment on a wide range of sexual behaviours and in broader populations. The first phase (PARTNER1) followed 888 serodiscorant couples where the infected partner was on

effective treatment (of which 340 were GBM) and reported on 1,238 couple-years of follow-up. There were zero transmissions reported. Despite this, due to the relatively low number of GBM couple-years follow-up accumulated (compared to heterosexual couples), the upper 95% CI limit for the transmission rate for GBM was significantly higher than for heterosexual couples: 0.84 and 0.46 per 100 couple years-years of follow-up, respectively. Consequently, the results did not constitute sufficient evidence to conclude that risk among GBM couples, where a partner is on effective HIV treatment, is effectively zero (as it could in a heterosexual context).

To resolve this, the PARTNER study devised a second phase (PARTNER2; Rodger et al., 2019) in which it only recruited GBM couples. This phase included 777 couples and a total of 76,088 episodes of CAI. The results reported that there were 15 new HIV infections among those who were seronegative at enrolment; however, of these infections none were phylogenetically linked within-couple transmissions and therefore there were zero within-couple transmissions. These results have determined that it is not possible for an HIV-positive partner on effective HIV treatment (resulting in undetectable levels of HIV viremia in the blood) to sexually transmit HIV. This led to the multi-national campaign, which is endorsed by the medical community, 'U=U' (undetectable equals untransmittable).

Prognosis

Life expectancy is defined as 'the average number of years an individual of a given age is expected to live if current mortality rates continue to apply' (Porta, 1998). During the early years of the epidemic when effective antiretroviral therapy did not exist, the median time of survival following a diagnosis of AIDS rarely exceeded 20 months (Eiden and Lifson, 1992). A large-scale retrospective study (Babiker et al., 2000) has estimated that the median time from seroconversion to AIDS and death is approximately 9 and 10 years, respectively, but varies by age at seroconversion (with those aged >50 generally progressing rapidly). HIV

was therefore commonly referred to as a ‘death sentence’ in those early years of the epidemic.

Life expectancy for those with an HIV infection remained poor for much of the 1980s and 1990s, despite rapid advances in treatment (which are discussed below). In 1997, HIV was in the top 10 causes of death worldwide, partly because treatments were initially largely ineffective and because they were not readily available in resource-poor countries, where HIV prevalence was higher (Nicholl & Gill, 1999). In the US in 1990, HIV/AIDS was the leading cause of death among adults aged 25-44 years old and was responsible for 61% of all men within that age parameter who died in San Francisco, California (Selik et al., 1995).

However, there has been a plethora of studies that have since estimated that life expectancy of people infected with HIV is significantly improved (Freedberg et al., 2001; Walensky et al., 2006; Lima et al., 2007). It is now widely accepted that people infected with HIV infection who are diagnosed early (i.e., before significant damage to the immune system has been sustained) and access effective antiretroviral therapy, can expect a life expectancy comparable to that if they were HIV-negative (Marcus et al., 2020). However, comparable life expectancy does not mean one is free from co-morbidity. Those with a diagnosis of HIV infection are still more likely to have co-morbidities such as cardiovascular, kidney, liver, and bone disease as well as cancer and neurocognitive impairment (Lerner, 2020).

Treatment

Initial attempts to find effective therapeutics were characterised by treatment failures and disappointments (Sandstrom & Kaplan, 1987). However, in 1985 a diagnostic blood test which could identify antibodies specific to HIV was developed (Ward et al., 1986) and large-scale clinical trials were initiated to evaluate the use of azidothymidine (AZT) (Furman et al., 1986; St Clair et al., 1987). Despite AZT being associated with an increased survival at 24 weeks (Fischl et al., 1987), this apparent benefit was transient; by week 48 those survival

benefits were no longer observed (Fischl et al., 1990). Despite this, and with no other viable therapeutics available, AZT was approved for use in patients with advanced HIV infection in 1987. Among GBM – where the bulk of disease and death was occurring – anger grew at the lack of therapeutics and over reliance on AZT (New York Times, 1989), which was exacerbated by initial issues with patients in clinical trials being prescribed doses that were too high, causing severe toxicity in many (Yarchoan et al., 1986) (see figure 9).

Figure 9: Man protesting holding placard "Man cannot live on AZT alone", date unknown.

The next and most significant development in HIV treatment, came with the introduction of new drug classes that had a direct effect on the pathogenesis of HIV. This led to the concept of 'triple therapy' in 1995-1996, where three drugs from across the classes were used simultaneously to halt viral replication and therefore preserve the immune system. Within a few short years after the introduction of triple therapy, a dramatic decrease in morbidity and mortality associated with the inclusion of protease inhibitors to drug regimens was reported (Pallela et al., 1998; see figure 10). The improvement was so profound that it

was termed ‘The Lazarus Effect’ (Mubanda & Richey, 2012), referring to the Raising of Lazarus miracle in the Gospel of John (John 11:1-44) in the New Testament, in which Jesus raises Lazarus of Bethany from the dead four days after his entombment.

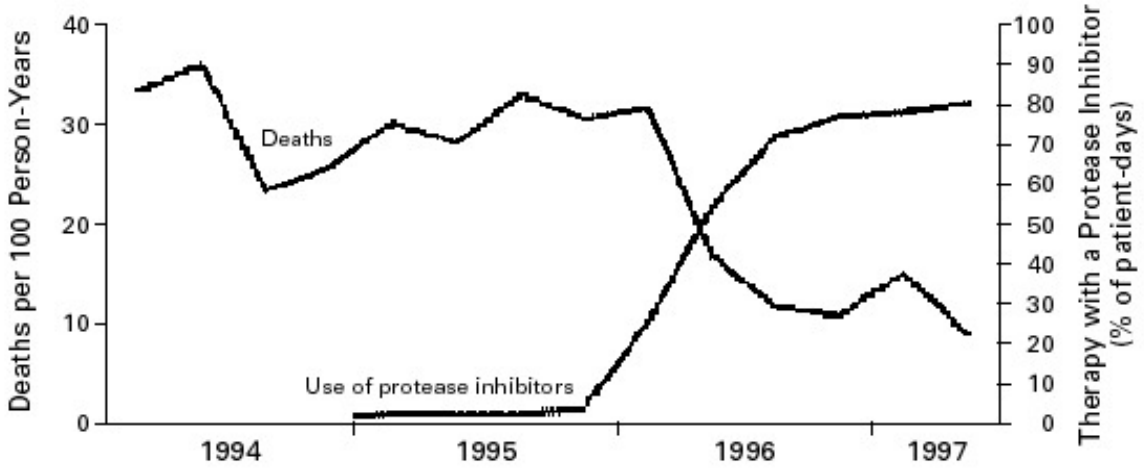


Figure 10: Mortality and frequency of use of combination antiretroviral therapy including a protease inhibitor among HIV-infected patients with fewer than 100 CD4+ cells per cubic millimetre, according to the Calendar Quarter, from 1994 through June 1997. From Palella et al., 1998.

Despite this, these drastic improvements were not without cost. These newly developed drug regimens were associated with significant short, mid, and long-term toxicities and other adverse effects. In turn, quality of life of patients on these drug regimens was significantly impaired, as the treatments required multiple daily dosing and a large quantity of pills for some time. In the last decade, however, there have been substantial improvements to the tolerability and effectiveness of HIV treatment, with the development of new classes of drugs. Single tablet, fixed-dose, once-daily combinations (Arribas et al. 2008; Sax et al., 2009) have become available, which have in turn improved adherence and thus treatment success. To date, there are now over 30 different HIV drugs and formulations across 6 different drug classes (i- Base,2019), with many more advances currently in development, such as long-acting injectable treatments (Phillips et al., 2021).

Epidemiology

Global Epidemiology. Globally, an estimated 38.0 million people are living with HIV infection in 2019 (WHO, 2019). In 2019, the WHO reported that 1.7 million people were newly infected with HIV and there were 700,000 HIV-related deaths. Although the number of people living with HIV globally is increasing, there are fewer new infections annually (23% reduction since 2010) and significantly fewer people dying because of HIV (39% reduction since 2010).

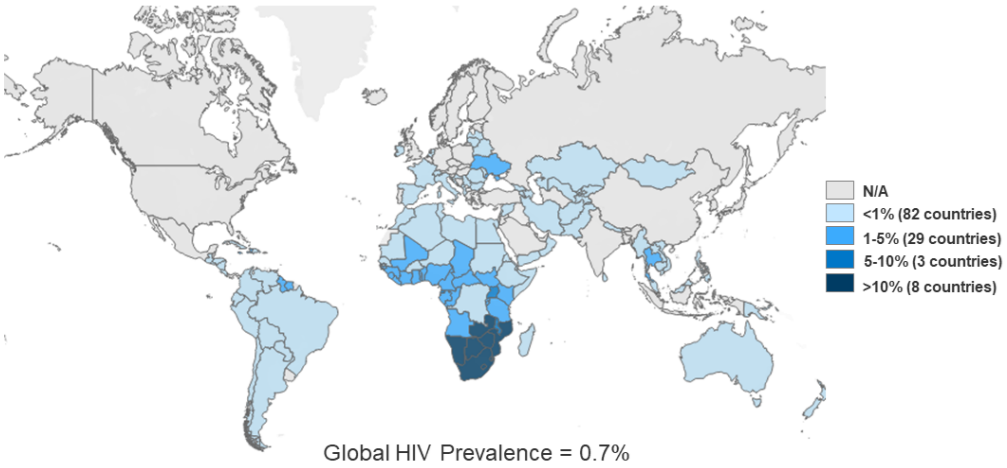


Figure 11: Adult HIV Prevalence, 2019

The UK Epidemic. Forty years have passed since the first AIDS case was reported in the UK, in 1981. During that time 164,621 people have been diagnosed (PHE, 2020) and there have been 25,352 deaths recorded. As of 2019, there is an estimated 105,200 people living with HIV in the UK, with 98,552 accessing HIV care. The proportion of people accessing HIV care in 2019 who acquired HIV through heterosexual sex (45,445; 46.5%) is very similar to the proportion of people who acquired HIV through sex between men (45,771; 46.8%). HIV prevalence is significantly higher in urban settings, especially those with large gay communities, such as London, Brighton, and Manchester (see figure 12).

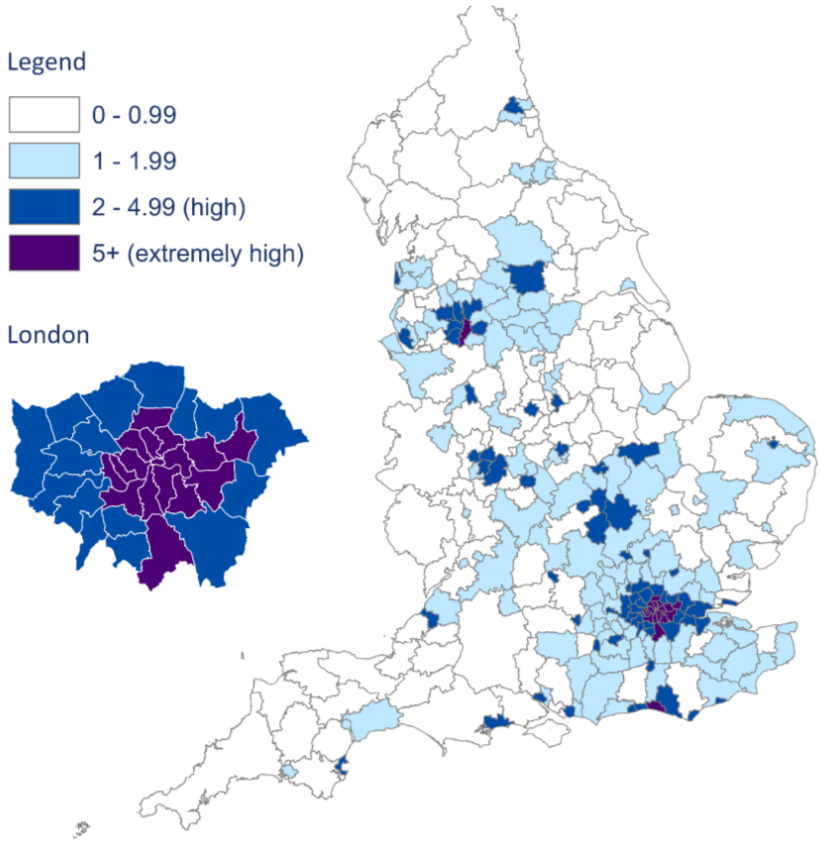


Figure 12: Diagnosed HIV prevalence (per 1,000 population aged 15 to 59 years): Local authorities in England, 2018

In 2019, there were 4,139 people newly diagnosed with HIV infection in the UK (see figure 13). New diagnoses have continued to decline in the last decade with a substantial decrease over the past two years; decreasing by 10% between 2018 and 2019, and by 34% since an observed peak number of infections in 2014 (6,312 newly diagnosed).

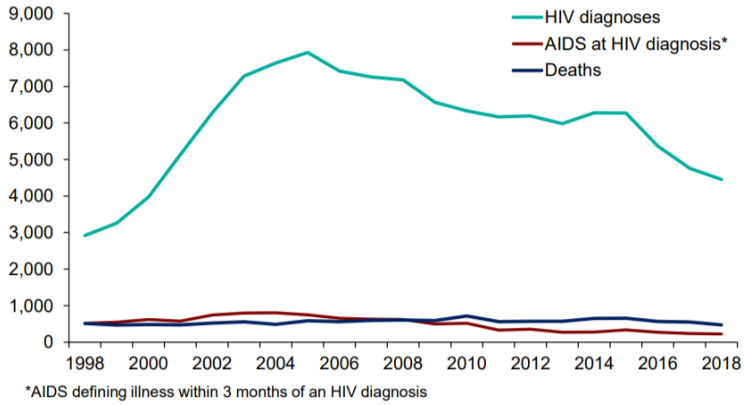


Figure 13: Number of new HIV diagnoses, AIDS at HIV diagnosis* and deaths in people with HIV: UK, 1998 to 2018

The UK epidemic is like that of other European countries and the US, in that GBM are disproportionately affected. To date, there have been 74,485 diagnoses of HIV in GBM throughout the UK, and 13,498 deaths (PHE, 2020). In 2018, 1,908 GBM were newly diagnosed with HIV, making up 43% of all new HIV diagnoses (see figure 14). This number has significantly reduced by 25% since a peak in 2015 and reflects the success of increased HIV testing and increase uptake in HIV treatment. Furthermore, the introduction of PrEP, which will be discussed later in this chapter, is also likely contributed.

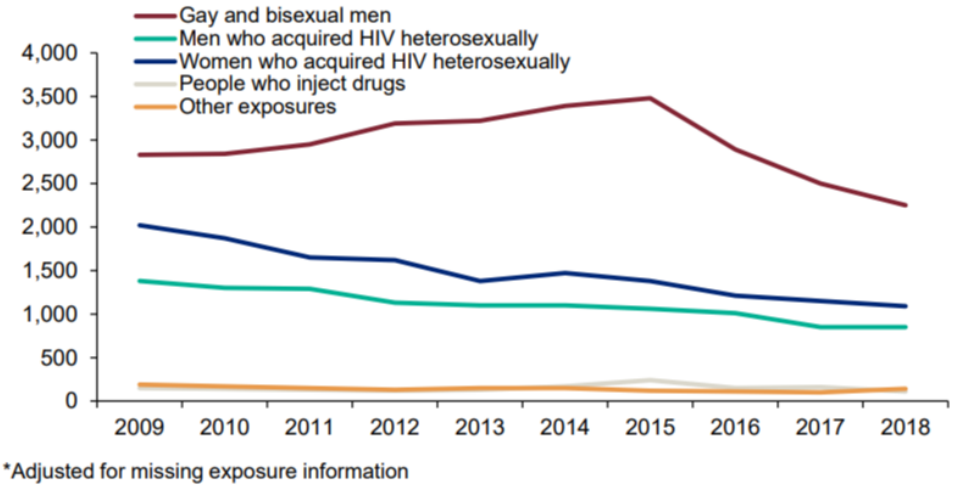


Figure 14: Number of new HIV diagnoses by exposure group*: UK, 2009 to 2018

Despite high prevalence and disease burden in GBM in the UK, HIV diagnoses have continued to decline since 2015 and are now at a 20-year low (PHE, 2020). In London, new diagnoses have fallen by 52% (from 1,415 in 2015 to 736 in 2018). This is particularly significant given that diagnoses had previously been increasing year on year from 2,820 in 2008 to 3,390 in 2015 (PHE, 2016, 2017). The reported drop has been linked to five sexual health clinics in London, including 56 Dean Street in Soho, the largest sexual health and HIV clinic in Europe, where diagnoses fell by 71% (PHE, 2019). In a comment to The Lancet, Consultant Physicians from the clinic attributed this success to the use of PrEP, as well as increased testing and earlier provision of anti-retroviral therapy for those who were diagnosed (Nwokolo, Whitlock, & McOwan, 2017).

Summary

Although it is evident that HIV has been transformed from a terminal illness to a chronic infection, with increasingly favourable outcomes, aided by effective treatments, HIV prevention remains imperative in the global fight against this disease. The next part of this chapter will discuss the history and various approaches to HIV prevention, as applied to GBM.

Part II: HIV Prevention

During the early years of the AIDS epidemic, it was those who were diagnosed with the disease, along with carers in their communities, who organised the initial preventative responses, through the production of leaflets and posters (see Figure 15) to disseminate knowledge, albeit some of it speculative (King, 1993). Subsequently, groups of GBM set up community groups which continued efforts to prevent infections (Merson et al., 2008). However, in the years that followed, aided by political will, global awareness, and a substantial increase in resource, HIV prevention became central to the response in the international community.

Figure 15: Safer Sex, Don't Dream It... Do It! Terrence Higgins Trust. Leaflet, 1987

For HIV prevention to have positive outcomes, it needs to be informed by knowledge of the virus, as well as broader determinants of the disease; specifically, the socioeconomic, cultural, and environmental factors that influence the transmission of HIV, at an individual and population level. Consequently, HIV prevention is a combination of biomedical, psychological, and structural interventions. For a strategy to be effective, it must be tailored to the context and based on scientific evidence (Piot et al., 2008). Those countries who have seen significant reductions in reducing HIV infection have used a combination of these approaches in a tailored and evidence-informed way (Green et al., 2006; Okie, 2006).

Condoms

Safer Sex. Although the term 'safe sex' has existed in the English language since the 1930s, the use of the term as applied to prevention of infection was first used in a 1984 publication discussing the psychological effect AIDS may have on GBM (Blair, 2017). Although safe sex is an umbrella term that covers all practices that mitigate risk of infection

(and in a heterosexual context, pregnancy), it has become synonymous with the male condom in the context of HIV prevention.

Condoms have been the mainstay of HIV prevention from the beginning of the epidemic. The evidence base for the effectiveness of the male condom as a physical barrier to HIV has significantly grown in the years that followed. As such, condom education and distribution constitute the single most significant component of HIV prevention in all countries and for all at-risk populations, such as GBM (WHO, 2015). A report compiled by the US National Institutes of Health (NIH) published in 2000, estimated that the male condom reduces HIV transmission by approximately 85% relative to risk when condomless, putting the seroconversion rate at 0.9 per 100 person-years with condom, down from 6.7 per 100 person-years without (NIH, 2000). The WHO has also reviewed the available evidence and estimated the male condom to reduce HIV transmission by 80-95% (WHO, 2008). Despite an impressive reduction in HIV transmission yielded by condoms, the effect size is significantly less in the context of receptive anal sex (Smith et al., 2015).

However, although the known failure rate of condoms, GBM were encouraged to believe that using a condom was ‘safe sex’ and they could continue engaging in anal sex with multiple or anonymous partners. Although condoms were (and are) marketed as prevention, in fact they are part of a ‘risk reduction’ strategy. Whilst condoms have been highly effective at curtailing new infections at a population level, it is likely that they were adopted as a compromise (O’Leary, 2014). Specifically, it is argued that the principal goal of HIV prevention for some gay activists was the defence of the gay sexual revolution, and since gay liberation was founded on: “...sexual brotherhood of promiscuity... any abandonment of that promiscuity would amount to a communal betrayal of gargantuan proportions” (Rotello, 1997, p109). Furthermore, it is documented that in the early days of the epidemic those involved in HIV prevention efforts among the gay community were:

> "to encourage condom use rather than attempt to persuade them to abandon anal intercourse... AIDS educators have a responsibility to aim only for the minimum necessary changes in individuals' lives which are needed to reduce the risk of getting AIDS" (Rotello, 1997, p109).

It was assumed by those external to the gay community that the fear of contracting an incurable, debilitating disease would be enough to motivate GBM to refrain from 'unsafe sex'. Despite the 'fear factor' having a huge impact (which will be discussed in detail later in this chapter), some GBM sought to romanticise HIV infection and openly reject the notion of 'safe sex' and by extension, condoms. HIV positive status was often portrayed in gay publications as more fun. An editorial in *Steam*, a magazine aimed at GBM, quotes a man who has been positive since the early years of the epidemic: "I'm so sick and tired of these Negatives whining about how difficult it is to stay safe. Why don't they just get over it and get Positive" (Rotello, 1997). Safer sex was also criticised as being some sort of antidote to sexual pleasure and curtailed gay and bisexual self-expression. Scott O'Hara, the HIV-positive Editor of *Steam* (who subsequently died of AIDS in 1998) wrote:

> "One of my primary goals is the Maximisation of Pleasure, and just as I believe that Gay Men Have More Fun, so too do I believe that Positives have learned to have much more fun than Negatives. I'm delighted to be Positive... The Negative world is defined by fear, ours by Pleasure" (Rotello, 1997).

Reduced Adherence to Condoms. Despite their wide-spread adoption, condom use among GBM is now in decline and CAI is increasing, both in total instances and the number of different CAI partners over time (Frost et al., 2008; Galindo et al., 2012). According to the research, older GBM are less adherent to condoms and have expressed fatigue with regards to HIV prevention that focuses primarily or exclusively on condoms (Balan et al., 2013).

There are many plausible explanations for the recent decline in condom use. There has been a growth in the gay sub-culture of 'barebacking' (which describes intentional CAI). Epidemiological and behavioural studies have documented a growing prevalence in the practice, identifying GBM who, despite awareness of the risks of CAI, choose to have condomless sex, possibility in pursuit of increased sexual satisfaction (Carballo-Dieguez and

Bauermeister 2004), though motivations vary between age and ethnicity (Vosvick et al., 2016). As barebacking has become a normalised practice, promoted through gay pornography and the increased eroticism of CAI, GBM who normally use condoms for anal sex may feel pressure to engage in CAI (Halkitis et al., 2008; Adam et al., 2005).

The belief that condoms may reduce sexual and emotional intimacy is legitimate and therefore presents a challenge for HIV prevention efforts. Condoms are frequently cited by GBM as having a negative impact on their psychosexual functioning (Klassen et al., 2019). Condoms are often perceived as a barrier to sexual satisfaction and arousal, whereas CAI is privileged in facilitating sensation, physical pleasure, and deeper levels of eroticism (Golub et al., 2010; Eisenberg et al., 2011). This can be attributed to the sensuality associated with 'skin-to-skin' contact as well as the psychological significance that semen can have for some GBM and the sexual arousal that can ensue from exchanging semen (Jaspal, 2019). Vincke et al. (2001) describe semen exchange as 'a means of showing devotion, belonging, and oneness' (p.58). A desire for trust, intimacy, commitment, and love may provide further motivation, wherein CAI serves as a manifestation of these emotions and a representation of the depth of a given relationship (Eisenberg et al., 2011; Carballo-Dieguez et al., 2011).

Seroadaptive Behaviours

In recent years, GBM have developed various seroadaptive behavioural strategies to reduce their risk of HIV infection which whilst mitigating their sexual risk, may be contributing to a reduction in condom use (Grace et al., 2014). These strategies, which are possible due to the advances in biomedical approaches, include:

- Serosorting: Seeking out sexual partners of the same HIV status and/or engaging in specific sexual behaviours based on a partner's known HIV status (Frost et al., 2008).

- Viral load sorting: Actively seeking out partners with undetectable HIV viral load status or use this information to determine the sexual behaviours between serodiscordant partners (Prestage et al., 2012).
- Negotiated safety: When there is a monogamy agreement between primary partners or the exclusion of higher risk sexual behaviours (e.g., anal sex) outside of the primary relationship (Vosvick et al., 2016).
- Strategic positioning: When an individual takes the decision to be the insertive partner during anal sex as an HIV negative partner in CAI (Grace et al., 2014).

Although these seroadaptive behaviours are common among GBM, the efficacy of each is not well-studied; furthermore, for these strategies to be effective they rely on explicit communication, disclosure, and trust (Vosvick et al., 2016), and this can generate some anxiety and uncertainty. It has been established that many GBM tend to assume or infer the HIV status of their partners, without having explicit communication (Adam et al., 2005), which can generate false assumptions and lead to HIV transmission and/or discrimination. Furthermore, negotiated safety agreements between partners are not always adhered to by one or more of the partners, as a significant proportion of HIV transmissions (as much as 68%) occur within the context of primary relationships (Goldenberg et al., 2015).

HIV Testing

Alongside condoms, HIV testing has been a key prevention strategy since the test's inception in March 1985. It plays a critical role for two reasons: Firstly, it enables individuals to know whether they are HIV positive or not and to modify their sexual behaviour accordingly. Secondly, it provides an opportunity to the individual to have dialogue with a health care professional, which has the potential to increase knowledge as to how to manage one's HIV risk. Despite the choices available to GBM to test for HIV, there have been a

range of psychological and social factors that influence their experience of HIV testing and subsequent engagement. Evangeli, Pady, and Wroe (2016) conducted a quantitative systematic review of 62 studies. The review highlighted several psychological barriers to regular HIV testing:

- Fear of death and disease because of HIV infection can lead to some individuals preferring not to know their HIV status (Lorenc et al., 2011).
- Some GBM subjectively appraise their HIV risk as low due to a lack of knowledge regarding HIV risk factors and/or they do not self-identify as GBM (Bond et al., 2015).
- There is a correlation between endorsement of HIV-related stigma and reduced frequency of HIV testing among GBM (Li et al., 2012). Furthermore, GBM may avoid testing for HIV to avoid self-association with HIV stigma (Young et al., 2007).
- It is recognised that among ethnic minority GBM, prejudice, especially homophobia and racism, is associated with declining HIV tests (Bond et al., 2015).

Post-Exposure Prophylaxis

Post-exposure prophylaxis (PEP) is a biomedical approach to HIV prevention which involves prescribing a course of anti-retroviral therapy to patients after a high-risk HIV exposure. It is thought to be effective at preventing an exposed individual from seroconverting and therefore remaining HIV negative (Cresswell et al., 2006). The combination must be initiated within 72 hours post possible exposure and taken for a duration of 28 days.

Despite the concept of PEP being around for many years, it has remained a controversial prevention method with opponents citing concerns around serious side effects, increased

sexual risk-taking and that it undermines public health (Jaspal & Nerlich, 2016). There have been no randomised control trials involving human participants to determine how effective PEP is at stopping seroconversion, following a sexual exposure to HIV infection. However, there are retrospective studies that have demonstrated effectiveness following occupational exposure. Specifically, an early study (Cardo et al., 1997) followed up health care workers who used zidovudine following a possible occupational exposure and reported that PEP reduced seroconversion by 81% (with a confidence interval of 48-94%). Additionally, there have been various animal studies that have supported the notion that PEP is efficacious as an HIV prevention strategy (Tsai et al., 1995). In 2006 the UK's medical organisations that are responsible for establishing treatment guidelines relating to sexual health and HIV, the British HIV Association (BHIVA) and the British Association of Sexual Health and HIV (BASHH) published national guidance on the application of PEP in the context of sexual exposure. These guidelines have been updated multiple times since their inception, considering increased prevalence, but the current circumstances in which PEP is recommended, considered, or not recommended can be seen in Table 1.

Furthermore, although the UK's national guidance on the use of PEP clearly states that the treatment should not be used to alleviate anxiety regarding HIV, it has been noted that a substantial amount of PEP is prescribed to GBM in this context (Scholten et al., 2018).

Table 1

Situations in which post-exposure prophylaxis (PEP) is recommended, considered, or not recommended, as per British HIV Association national standards (BHIVA, 2015).

Exposure Route	Source HIV status			
	HIV positive		Unknown HIV status	
	HIV VL unknown/detectable (>200copies/ml)	HIV VL undetectable (<200copies/ml)	From high prevalence country/risk-group (e.g., GBM)	From low prevalence country/group
Receptive anal sex	Recommended	Not recommended	Recommended	Not recommended
Insertive anal sex	Recommended	Not recommended	Consider	Not recommended
Insertive vaginal sex	Consider	Not recommended	Considered	Not recommended
Fellatio with ejaculation	Not recommended	Not recommended	Not recommended	Not recommended
Fellatio without ejaculation	Not recommended	Not recommended	Not recommended	Not recommended
Splash of semen into eye	Recommended	Not recommended	Consider	Not recommended
Cunnilingus	Not recommended	Not recommended	Not recommended	Not recommended

PEP has remained a controversial preventative strategy. Jaspal and Nelrich (2016) examined representations of PEP in the British print media, a key source of information regarding health, science, and medicine, between 1997 and 2015. They identified 3 key social

representations of PEP. Firstly, in some articles PEP was represented as a straight- forward 'morning after pill' which can prevent HIV. Secondly, it was also represented as a dangerous public health initiative that had the potential to have counterproductive outcomes by fuelling high-risk behaviour. Finally, the third representation positioned health care workers as more worthy recipients of PEP and GBM as being less deserving of this preventative tool. Jaspal and Nelrich (2016) went on to argue that these representations in the British media, which were found to be usually absent of technical information about PEP and its mechanisms of action, may lead to a polarisation of perceptions of PEP, while stigmatising those who use PEP, and GBM in general.

Summary

HIV prevention, especially in the context of GBM, has evolved throughout the epidemic and involves a variety of innovative strategies and interventions, across a combination approach of biomedical, psychological, and social. Despite condoms initially being successful in curtailing new infections, psychological factors relating to desire for intimacy and optimal psychosexual functioning have resulted in a lot of GBM finding using them consistently a challenge. In the wake of an increase in condomless sex and rising infections, HIV prevention needed a new tool: PrEP. The next part of this chapter will discuss the new era of HIV prevention with the inception of PrEP for GBM.

Part III: Pre-Exposure Prophylaxis

PrEP is an innovative way for those who are HIV negative, but who are at high risk of acquiring it, to prevent HIV infection by taking a daily anti-retroviral pill. PrEP works by interrupting the life cycle of HIV to prevent viral infiltration of potential host cells. PrEP has been researched extensively with multiple 'at risk' groups and forms of HIV transmission,

including transmission from mother-to-child, post- occupational exposure among health care workers, and GBM.

In the early stages of research, Van Rompay et al. (2001) and Garcia-Lerma et al. (2008) found that use of antiretroviral drugs tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) pre-exposure "provided significant protection to macaque monkeys exposed repeatedly to an HIV-like virus" (Brooks et al., 2012, p. 87). In turn, these findings led to clinical trials of PrEP amongst high-risk populations, specifically GBM (which are each discussed below). In practice, oral PrEP is recommended as a two-drug regimen of TDF and FTC, co-formulated as a single pill (branded as Truvada®; Gilead, 2004), and taken in one of two ways: daily dosing or event-based dosing (BHIVA, 2018; WHO, 2017). Daily dosing involves taking one Truvada tablet daily and event-based dosing involves taking two Truvada tablets 2-24 hours before anal sex, then a subsequent Truvada tablet 24 hours and then 48 hours later (Molina et al., 2015); see figure 17.

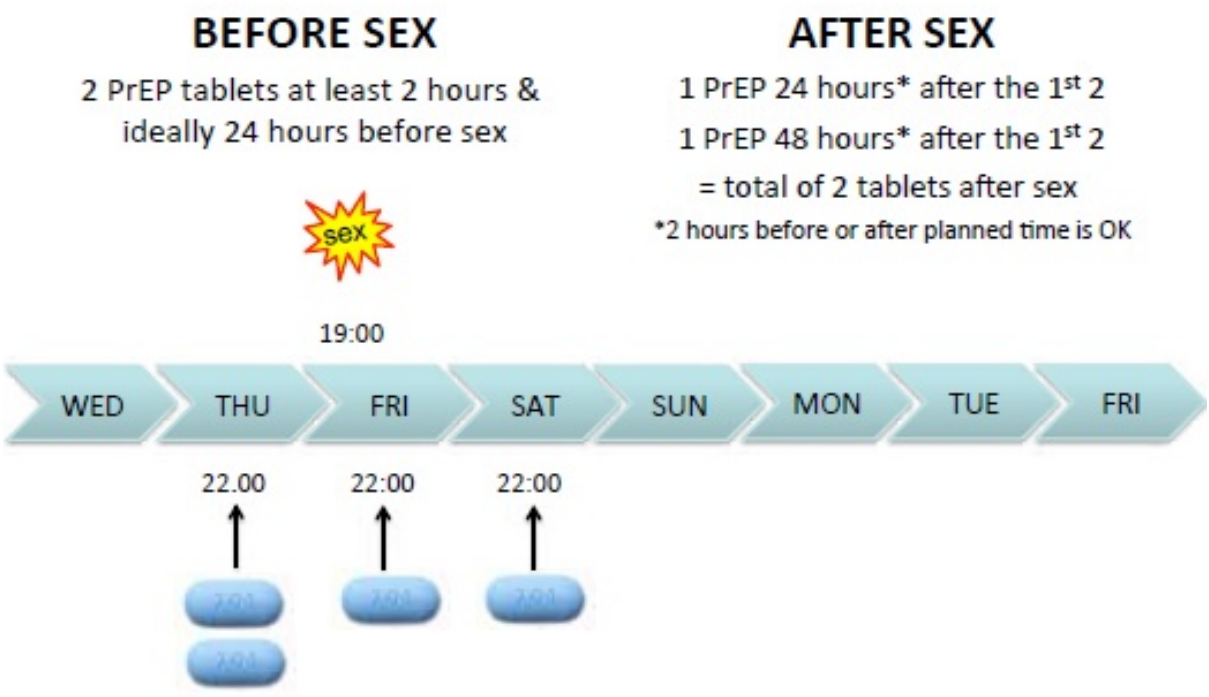


Figure 17: On demand dosing for once weekly risk.

It has been suggested that PrEP has infrequent but potentially harmful side effects such as nephrotoxicity and reduction in bone mineral density (BHIVA, 2018; Tan et al., 2017). It is also recognised that drug resistance may develop in those who initiate PrEP with undiagnosed HIV infection (Parikh and Mellors, 2016). Consequently, it is imperative that individuals engage with baseline and ongoing monitoring, which involves attending their sexual health clinic at least every 12 weeks for HIV and renal blood tests, as well as screening for other STIs (Tumarkin et al., 2019).

In the UK, the British HIV Association (BHIVA) and the British Association for Sexual Health and HIV (BASHH) published clinical guidance on the use of PrEP. PrEP is only recommended for use in GBM who are at an increased risk of HIV infection, through CAI (as well as other factors that would deem an individual to be 'high-risk'). The specific guidelines are detailed in Table 2. However, in practice, many GBM who do not meet the risk threshold have opted to take PrEP. To date, it is unknown what has motivated this decision, although it is thought that the associated psychological benefits of significantly reducing their HIV risk may be implicated.

Table 2

Summary table of recommendations for PrEP included in the BHIVA/BASHH 'Guidelines on the use of HIV pre-exposure prophylaxis (PrEP)' (BHIVA, 2018).

Recommend PrEP

(i) HIV-negative GBM and trans women who report condomless anal sex in the previous 6 months and on-going condomless anal sex.

(ii) HIV-negative individuals having condomless sex with partners who are HIV positive, unless the partner has been on ART for at least 6 months and their plasma viral load is <200 copies/m<.

Consider PrEP on a case-by-case basis

PrEP may be offered on a case-by-case basis to HIV-negative individuals considered at increased risk of HIV acquisition through a combination of factors that may include the following:

Population-level indicators

- Heterosexual black African men and women
- Recent migrants to the UK
- Transgender women
- People who inject drugs
- People who report sex work or transactional sex

Sexual behaviours/sexual-network indicators

- High-risk sexual behaviour: reporting condomless sex with partners of unknown HIV status, and particularly where this is condomless anal sex or with multiple partners
- Condomless sex with partners from a population group or country with high HIV prevalence (see UNAID definitions [1])
- Condomless sex with sexual partners who may fit the criteria of 'high risk of HIV' detailed above
- Engages in chemsex or group sex
- Reports anticipated future high-risk sexual behaviour
- Condomless vaginal sex should only be considered high risk where other contextual factors or vulnerabilities are present

Clinical indicators

- Rectal bacterial STI in the previous year
- Bacterial STI or HCV in the previous year
- Post-exposure prophylaxis following sexual exposure (PEPSE) in the previous year; particularly where repeated courses have been used

Drug use

- Sharing injecting equipment
- Injecting in an unsafe setting
- No access to needle and syringe programmes or opioid substitution therapy

Sexual health autonomy

Other factors that may affect sexual health autonomy

- Inability to negotiate and/or use condoms (or employ other HIV prevention methods) with sexual partners
- Coercive and/or violent power dynamics in relationships (e.g., intimate partner/domestic violence)
- Precarious housing or homelessness, and/or other factors that may affect material circumstances
- Risk of sexual exploitation and trafficking

Access to PrEP in the UK

The WHO updated their guidelines to recommend HIV PrEP as an additional HIV prevention strategy (WHO, 2015). Consequently, several countries have included PrEP in their national guidelines. In the USA, which was the first country to introduce PrEP in July 2015, there were an estimated 100,000 people taking PrEP in 2017 (Mera et al., 2017). Australia recruited 6500 patients over three clinical trials, with the number of people on PrEP

rapidly increasing (Traeger et al., 2019). Belgium has recently made the decision to make PrEP available to high-risk populations via a reimbursement scheme (PrEPWatch, 2019). In the UK, Scotland was the first to make PrEP available through the NHS, where 2,560 people accessing PrEP (97% were GBM) up to 2019 (NHS Scotland, 2020). In England, the provision of PrEP has been controversial. Initially, NHS England refused to fund it but later lost a high-profile High Court legal battle (National AIDS Trust v. NHS England, 2017).

In response to the High Court ruling, NHS England implemented PrEP via another clinical trial, namely the IMPACT trial. In October 2017, the IMPACT trial launched with the aim of recruiting a maximum of 13,000 high risk people from over 200 sexual clinics. Unfortunately, the demand for the trial far outweighed supply and the trial quickly become oversubscribed, with reports of some GBM travelling elsewhere in the country to access a space on trial (NHS England, 2019). In February 2019, NHS England announced that it was doubling the number of spaces on the trial to 26,000. Despite this, demand continued to outweigh supply which has led to a large cohort of GBM sourcing PrEP are independently.

In the UK it is legal to buy up to a 3-month personal supply of PrEP without the need for a prescription (IwantPrEPnow, 2019). This has led to a large cohort of GBM accessing PrEP through online pharmacies via a community-led website (www.iwantprepnow.co.uk). Subsequently, sexual health clinics started offering PrEP monitoring on the NHS (NHS England, 2017) to mitigate the risk to those taking the drug without appropriate monitoring. Furthermore, some NHS clinics offered private prescriptions for generic PrEP to try and increase access to PrEP in a safer way. For example, 56 Dean Street in Soho, developed ‘PrEP Shop’ and by August 2019 was providing generic PrEP to 8,459 GBM (McOwan, 2020). Whilst there are undoubted benefits to this with regards to increasing access to PrEP and subsequent reduction in HIV infection both at an individual and population level, this

does mean that GBM who are not high risk (i.e., would not be eligible for PrEP on the NHS) are accessing PrEP.

In August 2019, NHS England gave clinics the go ahead to offer PrEP on the NHS. At 56 Dean Street in Soho, they had started 12,500 GBM on NHS PrEP by the end of November 2019 (McOwan, 2020), signalling how popular PrEP is among GBM. As this is a very new development, the NHS has yet to collate and report official statistics as to how many GBM are accessing PrEP in the UK.

GBM & PrEP: The Clinical Trials

The iPrEx Study. The first large scale clinical trial of PrEP was called the iPrEx study (Grant et al., 2010), which was a Phase 3, randomised, double blind, placebo-controlled, multi-centre trial. The trial assigned 2,499 GBM and 339 trans-female adults to either take a combination of TDF-FTC (n=1251) or placebo (n=1248). Primary outcome was HIV infection with a total of 3324 person-years of follow-up. Over the duration of the study, 100 participants seroconverted to be become HIV positive: 36 in the TDF-FTC arm and 64 in the placebo arm, representing a 44% (95% CI 15-63) reduction in HIV incidence using a modified intention-to-treat (ITT) analysis, excluding those confirmed HIV positive at randomisation. Grant et al. (2010) also reported that efficacy was higher in the per-protocol analysis; at visits where adherence was >50% by self-report and pill count/dispensing, efficacy was 50% (95% CI 18-70).

The PROUD Study. The PROUD study (McCormack et al., 2016) was a Phase 3, randomised, open-label, multi-centre trial conducted at 13 sexual health clinics across England. The study recruited a total of 544 GBM who were randomly assigned to either the immediate arm (where they received daily FTC-TDF immediately; n=275) or the delayed arm (where they were given no drug for the first 12 months of enrolment; n=269). The primary outcomes were time to accrual of 500 participants and retention at 12 and 24 months; HIV

infection was a secondary outcome. The interim findings from the study were so compelling that the trial steering committee recommended that all delayed arm participants should be offered the study drug, as it would be unethical to continue depriving those enrolled in this arm. A total of 23 participants became infected with HIV over the course of the study: three in the immediate arm and 20 in the deferred arm (where they received no study drug), representing a rate difference in HIV infection of 7.8 per 100 person-years (90% CI 4.3-11.3). The relative risk reduction was 86% (90% CI 9-23) and the number needed to treat over 1 year to prevent one HIV infection was 13 (90% CI 9-23). Significantly, of the three participants who seroconverted in the immediate arm, one was thought to have acquired the infection prior to enrolment and the other two were not taking the medication. Protection against HIV in the context of perfect adherence was therefore estimated to be close to 100%.

The IPERGAY Study. The IPERGAY study (Molina et al., 2015) was a Phase 3 double-blind, randomised, multi-centre trial conducted in France and Canada. It enrolled 414 GBM and randomly assigned them to either receiving an on-demand regimen (n=206) or placebo (n=206). The on-demand regimen involved taking a double dose of TDF-FTC 2-24 hours before sex, and a daily dose during the periods of sexual risk and for 48 hours (two doses) after the last sexual risk. Participants were followed up every 8 weeks for HIV testing and risk- reduction advice, and every 6 months for testing for bacterial STIs for a total of 431 person- years follow-up. The primary outcome was HIV infection. As in the PROUD study, at the interim review, the placebo group was discontinued, and all study participants were offered study drug. Over the duration of the study, there were 16 new HIV infections: two in the TFD- FTC arm and 14 in the placebo arm, representing a relative risk reduction of 86% (95% CI 40- 98%) in the ITT analysis.

There have other phase 2 studies (Grohskopf et al., 2013), randomised pilot studies (Hosek et al., 2013; Mutua et al., 2012), open-label studies (Grant et al., 2014; Molina et al.,

2017) and observational studies (Hoornenborg and de Bree, 2017) that have all reported similar efficacy in protection against HIV in GBM who take the drug as prescribed. Despite this, the adoption of PrEP has been met with some resistance.

The Impact of PrEP on GBM

Risk Compensation. Despite evidence clearly suggesting that GBM who adhere to PrEP significantly reduce their risk of HIV infection, along with endorsement from the WHO (WHO, 2015), the intervention has not been met without criticism or scepticism. Specifically, in response to a Lancet HIV editorial: "PrEP: why are we waiting?" it was suggested that clinicians and policy-makers lacked information regarding the "normative aspects" of PrEP use (Jansen et al., 2017). They went on to suggest that the reason for PrEP not being widely implemented was lack of information regarding "people's own responsibility to use a condom, the relevance of being free of fear of HIV infection when having sex, and the relative importance of preventing HIV infection versus a possible rise in other sexually transmitted infections because of reduced condom use" (Jansen et al., 2017). This quote makes explicit the points that have held PrEP implementation back: moral judgement of sex and HIV prevention as a means of controlling sex (Golub et al., 2019).

In the last decade, other preventative strategies and interventions have all been met with similar scepticism due to their perceived risk of being responsible for behaviour change that could lead to an increased risk and thus counteract the benefits yielded by the prevention strategy. For example, the oral contraceptive pill in the 1950s (Watkins, 2001), the use of penicillin to cure syphilis in the 1960s (Farley et al., 2003), needle exchange programmes for people who inject drugs in the 1980s and 1990s (Wood et al., 2008), the emergency contraceptive pill (Raymond and Weaver, 2008), and more recently the UK's targeted HPV immunisation programme (Kasting et al., 2016). Despite PrEP having a robust and

impressive evidence-base for preventing HIV infection among GBM, it has, in common with other the other strategies mention above, aroused concern regarding 'risk compensation' (Auerback and Hoppe, 2015; Koester et al., 2017; Millam et al., 2019).

Risk homeostasis is defined as 'a system in which individuals accept a certain level of subjectively estimated [or perceived] risk to their health in exchange for benefits they expect to receive from [an]... activity' (Wilde, 1998). In accepting a particular level of risk of an adverse event, individuals maintain an approximate risk set point. However, the introduction of an intervention that reduces the perceived risk of the behaviour or activity (i.e., PrEP) may cause a person to increase other risk behaviours – this is termed 'risk compensation' (Wilde, 1998).

Risk behaviour has been measured across various outcomes, such as STI diagnoses, frequency of CAI and total number of sexual partners. The most clinically relevant outcome is STI diagnoses, as these have been deemed a reliable proxy to sexual behaviour. Furthermore, self-report of sexual behaviour is subject to reporting bias and is therefore less reliable. In the placebo-controlled trials, which by their design controls for behaviour, it is not possible to ascertain the impact of PrEP on behaviour, as the participants were unaware if they were talking the active drug or not. However, it is possible to evaluate the impact of risk-reduction interventions provided to the participants, and there were demonstratable benefits in iPrEx (Grant et al., 2010) and the CDC MSM Safety Study (Hosek et al., 2017).

In the iPrEx study, both arms reported increased condom use over the course of the study and reported condom use did not differ between arms ($p=0.97$) (Grant et al., 2014). The observed reduction in risk behaviours may have resulted from most of the participants coming from populations with poor access to risk-reduction support. In IPERGAY, there were no significant differences between the arms in the proportion of receptive CAI ($p=0.40$) and bacterial STIs ($p=0.01$). However, there was a marginal, yet significant, decrease in the

self-reported number of sexual partners in the previous 2 months in the placebo arm, when compared to the treatment arm (7.5 vs 8; p=0.001) (Molina et al., 2015; Sagon-Teyssier et al., 2016).

In the PROUD study, in which participants knew whether they were taking the study drug and that it was at least partially effective, there was no difference between the immediate and delayed arms in the total number of sexual partners (p=0.57) in the 3 months prior to the 1-year questionnaire, but a greater proportion of the immediate group reported receptive anal sex without a condom with 10 or more partners compared to the delayed arm (21% vs 12%, p=0.03). There was no difference in the frequency of bacterial STIs during the randomised phase (p=0.74). However, it should be noted that the study only recruited very high risk MSM and therefore their sexual behaviour was considered high risk prior to enrolment, irrespective of which arm they were randomised to, thus at increased risk of STIs.

Despite these findings from the clinical trials, there have been many other observational and epidemiological studies since PrEP has become increasingly popular among GBM and its access widened. These studies do suggest that CAI and incidence of STIs increase among GBM who use PrEP. Specifically, Rendina et al. (2018) examined changes in rectal STI incidence and behavioural HIV risk before, during, and after PrEP in a national sample of GBM in the US. Whilst they found that there was no change in the odds of rectal STI during PrEP use or after discontinuation compared to before uptake, they did find, compared to before PrEP use, a 156% increase in CAI with casual partners and a 410% increase in receptive CAI with serodiscordant partners while on PrEP. A study by Morris et al. (2018), which included GBM from California in the US, reported that the incidence rate of syphilis was over 3 times higher among those highly adherent (>1246 fmol/punch, consistent with 7 doses per week) to TDF-FTC at weeks 12 and 48, compared to those not highly adherent. Another study by Traeger et al. (2018) examined patterns and predictors of STIs in

GBM using PrEP and reported that STI incidence increased after PrEP use compared to before (IRR: 1.42; 95%CI 1.29-1.56).

Psychological Impact. Since PrEP has been introduced, most of the research among GBM has focused on acceptability, adherence, and risk compensation; there has been little attention devoted to understanding the psychological impact of using PrEP. Given the efficacy at reducing HIV transmission, even in the context of CAI, PrEP may confer psychological benefits to its users, such as lower sexual anxiety and enhanced sexual satisfaction and confidence.

The fear of acquiring HIV infection among GBM has been well researched and often linked to negative affect (e.g., anxiety). It has been noted that some GBM may have anxiety enduring for months after CAI (Godin, Naccache & Pelletier, 2000) and that some avoid testing for HIV for fear of receiving a positive test result (Lorenc et al., 2011). Despite this, given the effectiveness of PrEP in protecting users against HIV infection, it is plausible that these fears decrease as a result (Koester et al., 2017). Currently, there have been few studies published that have examined affect changes in GBM who use PrEP (Collins et al., 2017; Storholm et al., 2017); however, all these studies have observed decreases in anxiety associated with sex. GBM enrolled in an open-label extension (OLE), were noted to experience a reduction in anxiety relating to sexual behaviour and HIV, from a review of therapy progress notes (Hojilla et al., 2016). Similarly, interviews with GBM who were enrolled on another OLE trial revealed reduced fears of acquiring HIV and a reduction in HIV-related stress while taking PrEP (Collins et al., 2017; Koester et al., 2017). It is reported that GBM referred to PrEP as facilitating “an extra layer of protection”, “a safety net”, and “peace of mind”, which all convey a sense of more protection and a reduction in fear and anxiety associated with HIV infection.

It is evident that some GBM struggle to navigate between maintaining their HIV-negative status and experiencing adequate sexual satisfaction (Shernoff, 2006). The psychosexual factors associated with non-adherence to condoms have been discussed earlier in the chapter. As PrEP is highly effective in preventing HIV infection and condom use decreases among GBM who use PrEP, it may result in an increase in sexual satisfaction. Furthermore, by definition, PrEP users are engaging pro-actively in reducing their (and their partners') risk of HIV infection thereby taking control of their sexual health, which may lead to increase sexual esteem, through a more positive perception of their sexual ability and ability to effectively manage the sexual aspects of their selves (Maas and Lefkowitz, 2015). As has been discussed, those GBM who use PrEP are recommended to attend regular screening appointments at their sexual health clinic and this may lead to increased feelings of control over their sexual health and thus raise their sexual esteem (Whitfield et al., 2019).

Research into the impact of PrEP on sexual esteem is lacking; however, there have been relevant themes emerging in the existing body of research. Specifically, one participant from an OLE trial stated that "...[I] feel like I'm taking care of myself" and another commented that he felt more "comfort and confidence" as a direct result of attending to his sexual health (Storholm et al., 2017). Furthermore, other participants have stated that PrEP provided a "heightened sense of safety" (Hojilla et al., 2016) and "replaced feelings of worry" (Koester et al., 2017). Despite these findings, a quantitative study (Whitfield et al., 2019) in which 137 GBM were given psychological measures before initiating PrEP and after did not confer support. Specifically, following comparison of scores on the various measures pre-and-post and after adjusted multilevel models, there was a significant decrease in sexual anxiety ($p=0.003$) but no significant difference in sexual esteem or satisfaction.

It is evident that PrEP may afford those who take it some psychological benefits, such as reduced sexual anxiety and increased sexual satisfaction. It is well established that fear of

catching HIV infection is a common experience for GBM. The next part of this chapter will discuss the history, prevalence, and clinical aspects of 'HIV anxiety' in GBM.

Summary

It is evident that PrEP may afford those who take it some psychological benefits, such as reduced sexual anxiety and increased sexual satisfaction. It is well established that fear of catching HIV infection is a common experience for GBM. The next part of this chapter will discuss the history, prevalence, and clinical aspects of 'HIV anxiety' in GBM.

Part IV: HIV Anxiety

GBM and Anxiety Disorders

GBM account for an estimated 2.6% of the UK male population (Mercer et al., 2016). This diverse group experiences significant mental health inequalities. In epidemiological studies of the distribution of mental health difficulties across the population, GBM report more anxiety disorders than their heterosexual counterparts, including a higher lifetime prevalence of obsessive-compulsive disorder and agoraphobia (Stanfort et al., 2001) and higher 12-month prevalence of panic disorder (Cochran et al., 2009) and generalised anxiety disorder (Cochran et al., 2003). There is emerging evidence from a developmental perspective that suggests that early parental disapproval and gender nonconforming behaviour may be a factor in explaining increased prevalence of anxiety disorders in this group (Landolt et al., 2004; Skidmore et al., 2007). Furthermore, there is an already well-established and evidenced hypothesis that sexual orientation concealment and public self-consciousness predict anxiety disorders in GBM (Packankis and Goldfried, 2006; Packankis et al., 2008).

Minority Stress Theory

Minority Stress Theory (Meyer, 2003) suggests that societal stigma compromises GBM mental health through several psychosocial stress processes (see figure 18). Some of

these processes are specific to being gay or bisexual, such as internalised homophobia (Newcomb and Mustanski, 2010), stigma-based rejection sensitivity (Pachankis et al., 2008), and concealment of sexual orientation (Pachnakis, 2007). These cognitive, behavioural, and affective processes are associated with an increased risk of developing anxiety disorders and health-compromising behaviours, which further serve to perpetuate the risk of developing an anxiety disorder, such as alcohol use and sexual compulsivity (Feinstein et al., 2012; Newcomb and Mustanski, 2011). Although, other cognitive, behavioural, and affective processes are disrupted by GBM's stigma exposure, these are not specific to their sexual identity and serve as universal risk factors for developing anxiety disorders, as well as other mental health difficulties (Hatzenbuehler, 2009). Specifically, sexual minorities report more hopelessness, rumination, and social isolation compared to their heterosexual counterparts, even from an early age, which may account for why there are elevated rates of mental health difficulties and associated health-compromising behaviours across development (Hatzenbuehler et al., 2008; Saftren and Heimberg, 1999).

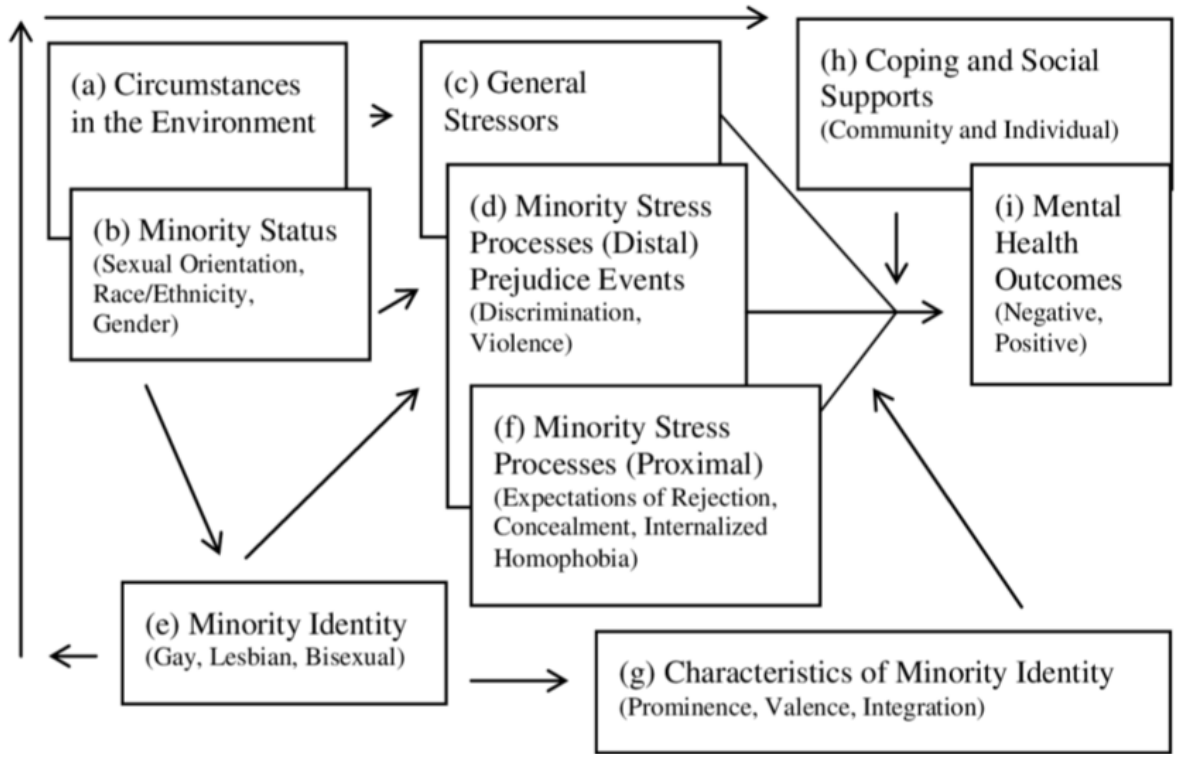


Figure 18: Minority stress processes in lesbian, gay, and bisexual populations (Meyer, 2003)

Internalised Homophobia

Internalised homophobia refers to the direction of societal negative attitudes towards the self (Meyer, 1995). Prior to the individual becoming aware of being gay or bisexual they internalise societal homophobic attitudes. When adolescents or young adults recognise their same-sex attraction, they will begin to question their presumed heterosexuality and may apply a minority label to themselves (e.g., gay). Concurrently, along with self-labelling it is suggested that they will also begin to apply negative attitudes to themselves and the psychologically damaging effects of societal prejudice take hold (Meyer, 1995). Thoits (1985, p222) describes the process and explains: "role-taking abilities enable individuals to view themselves from the imagined perspective of others". Link (1987, p97) describes a similar process observed in those diagnosed with serious mental health conditions and notes that those negative societal attitudes now apply to the self: "... [What] once seemed to be an innocuous array of beliefs...now become applicable to me personally and [are] no longer innocuous." It is therefore suggested that along with the emergence of a recognition on one's same sex attraction, a deviant identity (Goffman, 1963) begins to emerge that in turn compromises the psychological health of the GBM (Hetrick and Martin 1984; Stein and Cohen, 1984). Whilst it is recognised that internalised homophobia is likely to be most pronounced at the initial stages of recognising one's sexual identity, or early in the coming-out process, it is understood that it is unlikely to completely abate, even in the context of self-acceptance (Cass 1984; Troiden, 1989). As a result of the impact of early socialisation experiences and continued exposure to homophobic attitudes and beliefs, internalised homophobia remains an important factor in GBM's psychological adjustment throughout their life course (Gonsiorek, 1988; Nugesser, 1983).

As has been discussed, GBM have been associated with AIDS and HIV since the advent of the epidemic. It is evident that some GBM perceive the likelihood of them acquiring HIV as 'inevitable', through witnessing the epidemic unfold in their communities, as well as internalised homophobia (Jaspal, 2020).

HIV Anxiety in GBM

It is understandable that for the majority of GBM, the prospect of acquiring HIV infection would be extremely aversive, leading to proportionate behaviour change to maintain their HIV negative status (e.g., not engaging in CAI). Despite this, for a significant minority the pursuit to remain HIV negative prevails to such a level as to lead to disproportionate avoidance and reassurance seeking that would be deemed unnecessary by those around them (including HIV clinicians). Examples of this might include abstaining from all sexual contact, repeatedly taking HIV tests despite no objective risks and multiple previous negative results, inappropriate use of PEP and PrEP, extreme anxiety and checking after any form sexual contact, and body and symptom checking. Despite adopting these behaviours, some GBM may still erroneously believe themselves to be HIV positive. It is reported that in rare and extreme cases, this psychological distress can lead to deliberate self-harm and suicidal behaviours (Vuorio et al., 1990).

Since the early years of HIV and AIDS, fear has been reported among GBM, as well as other populations (Scragg, 1995). A critical review by Scragg (1995) found that the phenomenon was referred to using different terminology, diagnoses, and labels: 'pseudo-AIDS' (Miller et al., 1985); AIDS panic (Windgasson and Soni, 1987); and AIDS phobia (Jacob et al., 1989). Scragg, who is a UK-based clinical psychologist, referred to it as 'HIV illness phobia'. To date, there is no universally agreed terminology to describe the phenomenon; however, in clinical practice it is usually referred to as 'HIV anxiety' (Margetts, 2012). It is important to note that this term is restricted to anxiety over becoming

HIV positive and not due to delusional or psychotic beliefs, or 'AIDS variant Munchausen's syndrome' (Churchill et al., 1994).

Historically, along with the labels above, GBM presenting with these difficulties would often be diagnosed with hypochondriasis (Margettes, 2012). Contemporarily, there are various diagnostic labels that may, at least in part, describe HIV anxiety but it is Illness Anxiety Disorder (APA, 2013) that most adequately captures the experience and difficulties and it therefore this diagnosis that is most associated with HIV anxiety (see Table 3 for diagnostic criteria).

Table 3
Illness Anxiety Disorder classification and diagnostic criteria as per Diagnostic Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; 2013)

Illness Anxiety Disorder 300.7 (F45.21)

Diagnostic Criteria

A. Preoccupation with having or acquiring a serious illness.

B. Somatic symptoms are not present or, if present, are only mild in intensity. If another medical condition is present or there is a high risk for developing a medical condition (e.g., strong family history is present), the preoccupation is clearly excessive or disproportionate.

C. There is a high level of anxiety about health, and the individual is easily alarmed about personal health status.

D. The individual performs excessive health-related behaviours (e.g., repeatedly checks his or her body for signs of illness) or exhibits maladaptive avoidance (e.g., avoids doctor appointments and hospitals).

E. Illness preoccupation has been present for at least 6 months, but the specific illness that is feared may change over that period of time.

F. The illness-related preoccupation is not better explained by another mental disorder, such as somatic symptom disorder, panic disorder, generalised anxiety disorder, body dysmorphic disorder, obsessive-compulsive disorder, or delusional disorder, somatic type.

Specify whether:
Care-seeking type: Medical care, including physician visits or undergoing tests and procedures, is frequently used.
Care-avoidant type: Medical care is rarely used.

As I have previously argued in this part of the chapter, it is conceivable that anxiety disorders in GBM may be a result of minority stress and internalised homophobia. As cognitive-behaviour theory is proficient in providing explanation for cognitive, behavioural, and affective aspects of anxiety disorders, a variety of CBT-specific models applicable to HIV anxiety will now be discussed.

Cognitive-Behaviour Framework

Theoretical models and treatments based on cognitive behavioural therapy (CBT) have a critical role in the understanding, formulation, and intervention of anxiety disorders (e.g., post-traumatic stress disorder, Bisson and Andrew, 2007; panic disorder, Furukawa et

al., 2007; obsessive compulsive disorder, Hunot et al., 2007; hypochondriasis, Thomson and Page, 2007). To date, there is no theoretical model that is specific to HIV anxiety; however, there are several CBT disorder-specific models that give further insight into the conceptualisation and formulation of HIV anxiety. Specifically, the three models that lend themselves to HIV anxiety and will be discussed further are: specific phobia; health anxiety; and OCD.

Specific Phobia. For many GBM the fear of HIV is singular, and it therefore may be conceptualised as a specific phobia, which Jacob et al. (1989) historically referred to as 'AIDS phobia'. The DSM-V defining criteria for a specific phobia (APA, 2013) is detailed in Table 4.

Table 4
Specific Phobia classification and diagnostic criteria as per Diagnostic Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; 2013)

Specific Phobia 300.29

Diagnostic Criteria

A. Marked fear or anxiety about a specific object or situation (e.g., flying, heights, animals, receiving an injection, seeing blood).

B. The phobic object or situation almost always provokes immediate fear or anxiety.

C. The phobic object or situation is actively avoided or endured with intense fear or anxiety.

D. The fear or anxiety is out of proportion to the actual danger posed by the specific object or situation and to the sociocultural context.

E. The fear, anxiety, or avoidance is persistent, typically lasting for 6 months or more.

F. The fear, anxiety, or avoidance causes clinically significant distress or impairment in social occupational, or other important areas of functioning.

G. The disturbance is not better explained by the symptoms of another mental disorder, including fear, anxiety, and avoidance of situations associated with panic-like symptoms or other incapacitating symptoms (as in agoraphobia); objects and situations related to obsessions (as in obsessive compulsive disorder); reminders of traumatic events (as in post-traumatic stress disorder); separation from home or attachment figures (as in separation anxiety disorder); or in social situations (as in social anxiety disorder)

Using this diagnostic criterion, HIV would be considered the 'object' that is feared or, alternatively, the 'situation' being that one is HIV positive. In the DSM-V there are different subtypes, one of which is 'blood-Injection-Injury' (B-I-I). It is suggested that B-I-I phobias may have an evolutionary function (i.e., those who avoid puncturing their skin have a greater chance of survival) (Hamilton, 1995). It is therefore possible that a fear of an infection such as HIV could prove to be advantageous evolutionary (Margetts, 2013).

Irrespective of whether HIV anxiety is considered a B-I-I specific phobia, the two-factor learning theory model of phobias (Mowrer, 1960) may be applicable. Specifically, this theory suggests that anxiety is acquired through classical conditioning – initial pairing of a stimuli with an aversive experience, to generate an anxious response (e.g., fear).

Subsequently, this is then maintained by operant conditioning – an avoidance of the stimuli (either for what it represents or fear of the anxiety response) in the short-term leads to a subsiding of anxiety (and is therefore cyclical). However, in the long-term this prevents the individual from learning that the predicted adverse outcome will not be realised and/or their ability to cope is superior to their initial predication. It may also lead to selective attention and hyper-vigilance for the threat (i.e., HIV). This model is diagrammatically presented in Figure 19.

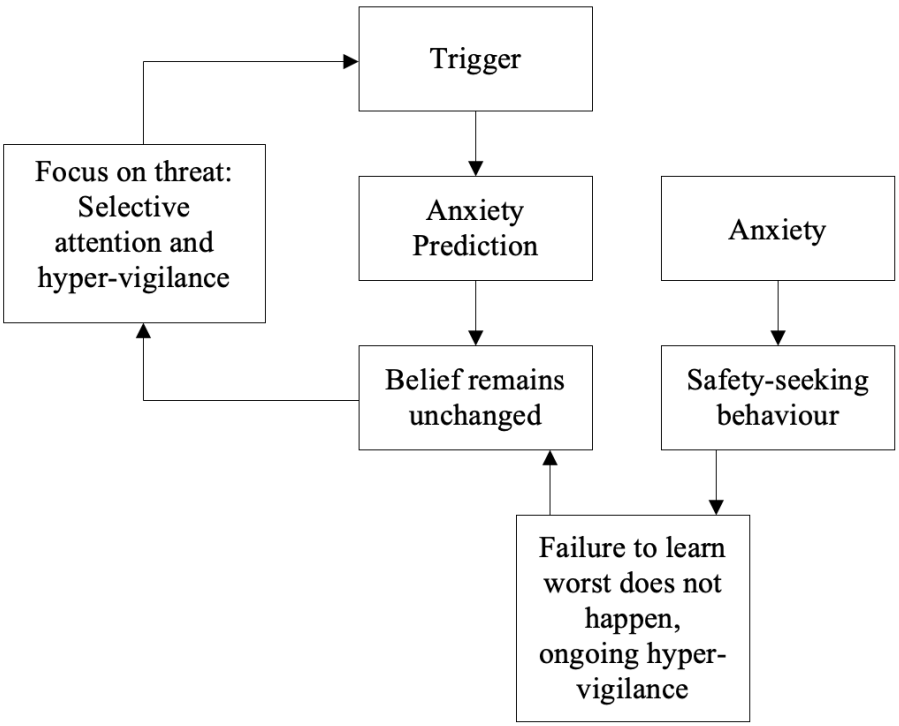


Figure 19: CBT model of specific phobia (Westbrook et al., 2007)

Further to conditioning, Rachman (1977) also proposed that 'vicarious learning' (e.g., observing fear through observing others) and 'negative information' are pathways to fear-acquisition. It is therefore both conceivable and understandable that GBM, with increased exposure to HIV-related information, in addition to perhaps observing others with the infection, may develop a fear of it. Despite this, the CBT model for specific phobia is not without its limitations. Specifically, it is exceptionally rare for people to be actively exposed

to the HIV virus; indeed, unlike other phobic objects the virus itself cannot be seen or touched (as in fear of animals) or transiently experienced (as in fear of flying). This therefore raises the question as to whether HIV can really be considered an 'object' or 'situation', as applicable to a phobia. In clinical practice, HIV anxiety tends to be characterised by a sustained anxiety about acquiring HIV infection, rather than an 'immediate anxiety response'. A further criticism of the model is that it does not account fully for the cognitive and behavioural aspects of HIV anxiety. Specifically, whilst some GBM do experience anxiety during sex, often the anxiety is experienced before or after engaging in the behaviour. It is argued that such elevated anxious anticipation is more in keeping with other anxiety disorders, rather than a specific phobia (Craske et al., 2009).

It is also common in clinical practice for GBM to not regard their anxiety as 'excessive or unreasonable'; indeed, some GBM consider their pursuit for repeated HIV testing, courses of PEP and abstinence as not only proportionate but vital to the preservation of their HIV negative status (Margetts, 2013).

Health Anxiety. It is often assumed that the health anxiety model (Warwick and Salkovskis, 1990) best explains HIV anxiety, especially if the anxiety is concurrent with fears of other illnesses, and cognitions related to the symptomatic profiles and death. Despite health anxiety (e.g., illness anxiety disorder) being the most widely adopted term for HIV anxiety in the field of CBT, it is diagnostically classified as a somatoform disorder (APA, 2013), not anxiety. See Table 3 for the DSM-V diagnostic criteria.

In relation to the diagnostic criteria for illness anxiety disorder, HIV can be considered as a serious illness. Specifically, as discussed in Part I of this chapter, although HIV is almost always manageable (in a UK context) and therefore not immediately fatal, it continues to pose a significant burden on the health of an individual. During seroconversion there are marked flu-like symptoms, including a maculopapular rash to the trunk, and so

misinterpretations of common colds and other relatively harmless viral illness represent an example of misinterpreting body symptoms. It is common for GBM to palpate their glands and check for rashes when concerned about the possible presence of HIV infection (Margetts, 2013). Furthermore, bodychecking and scanning can be deployed to discover possible infection routes (e.g., an ulcer in their mouth, micro abrasion on penis or perineum). Seeking reassurance from medical practitioners is also evident in those presenting with HIV anxiety: seeking out reassurance as to what constitutes a risk and procurement of HIV tests. The CBT model for health anxiety (see figure 20) contains the fear and avoidance components of the specific phobia model, whilst also incorporating behaviours observed in HIV anxiety, such as body checking and reassurance seeking.

This model considers developmental experiences (e.g., homophobia) that may lead to the formation of specific beliefs about oneself, others, and the world in relation to health (these are termed schemas). When presented with health-related stimuli (a critical incident), cognitive biases then distort health related perception and information, ultimately resulting in anxiety. To reduce the anxiety, the individual may engage in avoidance, as well as reassurance seeking and body checking. Because of the arousal process that is triggered, the physical manifestations of stress and anxiety may well be misinterpreted as a symptom of the feared illness (e.g., HIV), which perpetuates the anxiety about one's health.

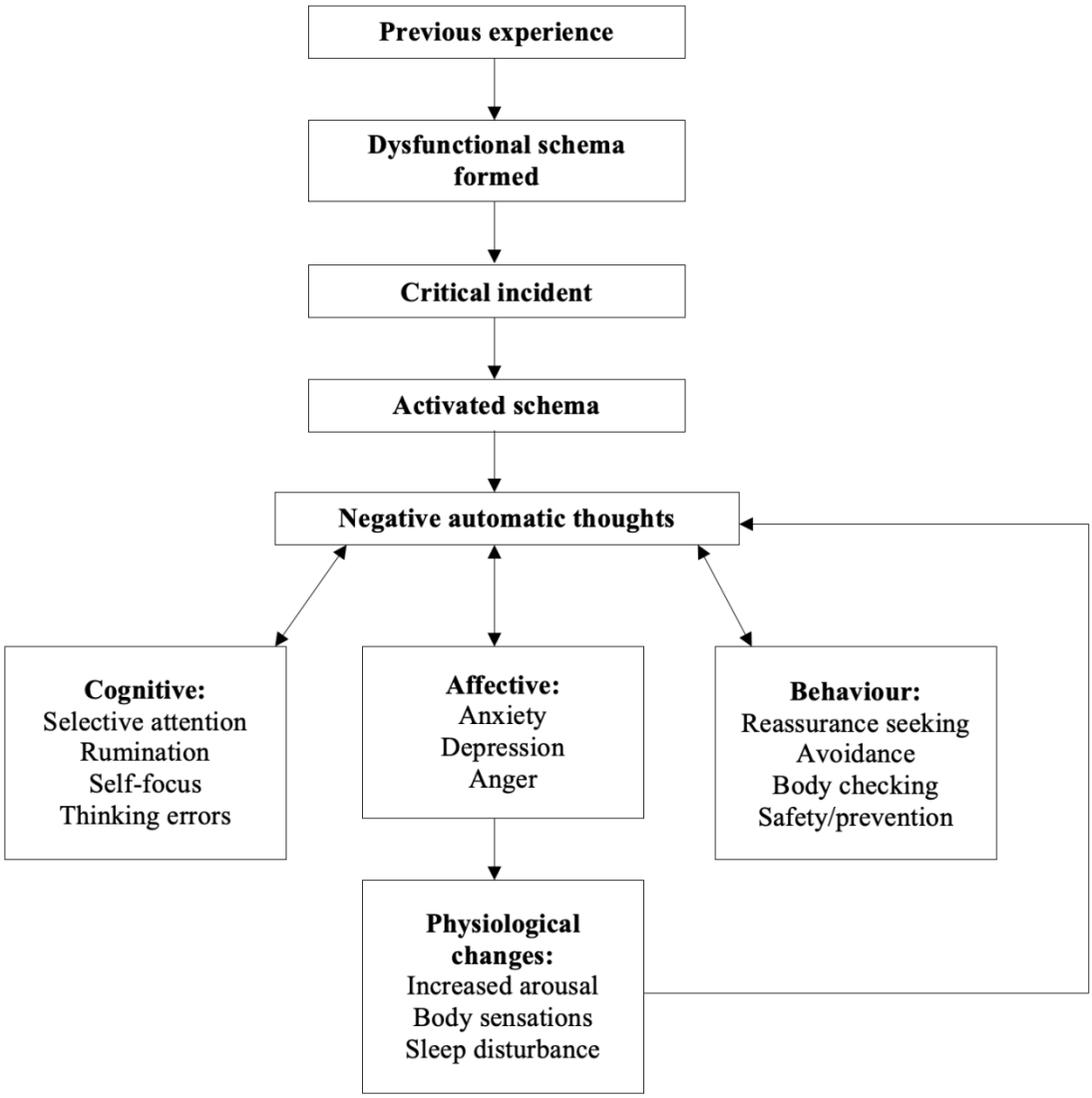


Figure 20: CBT model of health anxiety (Warwick and Salkovskis, 1990)

Salkovskis and Bass (1997) have suggested that fundamental to health anxiety is the over-valued beliefs around the likelihood and cost of illness, and under-valued perceptions of one's ability to cope with the illness. This is supported by a meta-analysis (Marcus et al., 2007) looking at cognitive and perceptual variables associated with health anxiety in which the authors found that cognitive biases in health anxiety led individuals to overestimate the frequency of serious illness, have more restricted beliefs as to what constitutes health (i.e., having HIV irrespective of treatment status is always bad), and make catastrophic misinterpretations of benign symptoms. Some GBM with HIV anxiety may inflate the

probability they will acquire HIV, believe that it would be profoundly catastrophic if they did, and assume that they would not be able to cope as a result.

Importantly, however, the health anxiety model is derived from and applied to anxiety related to unavoidable illness such as cancer, multiple sclerosis, and motor neuron disease. Whilst some GBM may consider HIV inevitable (as previously discussed), it is still objectively avoidable. Moreover, the CBT models for specific phobia and health anxiety omit any reference to cognitions around perceived responsibility for acquiring HIV and/or the ability to infect others (in stark contrast to medical conditions which spontaneously occur). In turn, these considerations around contamination and loci of control spur consideration from a CBT OCD perspective.

Obsessive Compulsive Disorder. The integrated schematic model describing the cognitive hypothesis of the origins and maintenance of OCD (Salkovskis et al., 1998) is represented in Figure 21. According to this model, early experiences lead to assumptions and beliefs about responsibility and danger. In turn, these are then activated by a critical incident, and intrusions (thoughts, images, urges or doubts) occur. Whilst these are normal, they are misinterpreted as a need for action. In turn, distress, attentional biases, neutralising actions (to try and cancel out the danger) and avoidant safety strategies (to prevent danger) all follow. Consequently, this results in the original intrusions not being challenged or appraised harmless, creating vicious cycles.

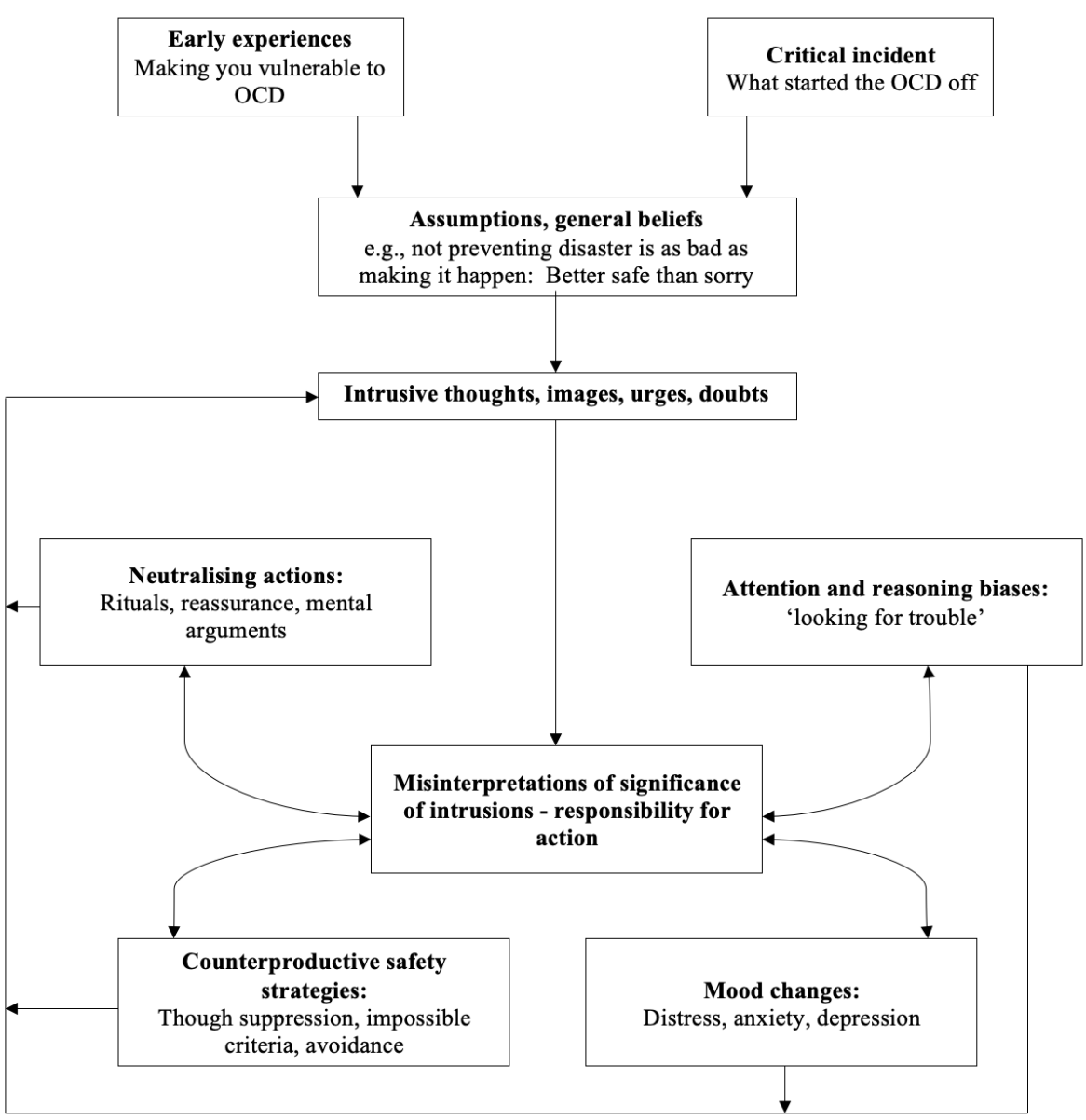


Figure 21: cognitive-behavioural model of OCD (Salkovskis et al., 1998)

The International Obsessive Compulsive Cognitions Working Group (OCCWG) have played a critical role in researching the assumptions and beliefs that are central to OCD (2003; 2005). The OCCWG have identified six key cognitive factors, which are listed in Table 5.

Table 5
Key cognitions in OCD (from Morrison and Westbrook, 2004, p102-103)

Domain	Belief
Thought-action fusion (TAF)	Likelihood TAF: *"merely having a 'bad' thought can produce a bad consequence"* Moral TAF: *"Having a thought about some bad action is regarded as morally equivalent to actually performing that action (often because it is taken as a hidden desire to perform that action)"*
Inflated responsibility	*"one has the power to produce or prevent negative outcomes. This results in the person feeling obligated to take every possible action to prevent the feared consequence, or to constantly monitor to make sure that nothing they have done or left undone could have a negative result"*
Control of thoughts	*"it is possible to control one's thoughts and images, and desirable or necessary to do so"*
Overestimation of threat	*'an exaggerated estimation of the probability or severity of harm"*
Intolerance of uncertainty	*"it is absolutely necessary to be certain, and that if one cannot be certain then one will find it impossible to cope"*
Perfectionism	"there is a right way to do everything and that it is one's duty to do it that way"

The OCCWG acknowledges that there is an overlap between the domains, and that they are not exclusive to OCD (insofar as they have been observed in other anxiety disorders). Therefore, it is the interaction and 'fixity' of these beliefs (e.g., how rigidly they are held by the individual) that is paramount (OCCWG, 1997). Specific to HIV anxiety are the inflated sense of responsibility (for maintaining their HIV negative status), overestimation of the threat (in relation to HIV), intolerance of uncertainty (in not knowing their HIV status) and perfectionism (HIV being conceptualised as an 'imperfection'). The notion of responsibility is very pronounced in HIV anxiety compared to other illnesses (Margetts, 2013); Scragg (1995), for instance, reported that guilt from perceived responsibility failure is a defining feature across HIV anxiety presentations.

Abramowitz et al. (2007) found that individuals with a diagnosis of OCD did not differ in belief about the probability of developing a serious illness or preoccupation with bodily sensations, when compared to those with a health anxiety diagnosis. However, their anxiety regarding health was lower due to not having elevated beliefs regarding catastrophic negative consequences of becoming unwell. In relation to obsession in HIV anxiety, these are like the general themes seen in OCD (e.g., contamination, health, order, sex, and religion [Rachman, 2003]).

The neutralising and counterproductive safety behaviours are deployed in consequence to the obsessions. Compulsions are grouped into wide ranging categories such as checking, washing, counting, 'confessing', ordering, and hoarding (Clarke, 2004). In relation to HIV anxiety, checking and washing are highly relevant: GBM with HIV anxiety may check their HIV status or the integrity of the condom repeatedly). Abramowitz et al. (1999, p537) distinguishes between:

> "...two different types of health-related concerns in OCD: (a) concern with illness stemming from environmental contaminants (e.g., AIDS), and (b) hypochondriacal concerns unrelated to external factors (e.g., brain tumour). Further, it appears that each type of concern is associated with a functionally related compulsive ritual."

Abramowitz et al. (1999) made parallels with Rachman and Hodgson (1980) who identified that cleaning rituals associated with OCD are 'restorative' and checking rituals are 'preventative'. In relation to HIV anxiety, avoidance rituals that could be considered 'preventative' may include PrEP or PEP, whereas 'restoration' may describe those GBM who believe that they are HIV positive and wish to be diagnosed to access appropriate treatment and support (thus leading to repeated HIV tests and reassurance seeking from clinicians) (Margetts, 2013).

Whilst the OCD CBT model does offer both theoretical and clinical insights into HIV anxiety, in common with the other two CBT models discussed, there is an absence of the role of stigma and shame in the manifestation of HIV anxiety.

Biopsychosocial Model of Shame. As discussed, disorder-specific CBT models do lend themselves, at least in part, to the conceptualisation of HIV anxiety. However, a challenge to each of the models is that they do not consider the shame and stigma that can be associated with HIV anxiety, such as that from revelations of a pattern of sex out of a primary relationship and subsequent feelings of guilt and shame. Specifically, Miller et al. (1988) found high levels of guilt and covert sexual experiences (e.g., GBM who were not 'out'). Similarly, Scragg (1995) made a similar observation. This therefore raises the possibility that HIV anxiety may be not only a fear of illness but a fear of shame from acquiring HIV or the behaviours (i.e., homosexuality) associated with the acquisition (Margetts, 2013).

It is important to note that shame is a transdiagnostic concept and has received recent theoretical and clinical interest in a range of mood disorders, with the development of compassion focused therapy (CFT; Gilbert, 2010a; Gilbert, 2010b). Gilbert (2010a) proposes that there are two forms of shame: external, referring to when other people judge one negatively; and, internal, when is when the judgement is directed towards oneself. The concept is derived from evolutionary ideas of 'social rank theory' (Stevens, 2016), in which some form of social competition (e.g., sexual partners) are linked to being attractive to others and ultimately to be included and chosen. If 'unattractive' on whatever parameter is being judged, then avoidance or rejection follows (Gilbert, 2006). The biopsychosocial model of shame is diagrammatically presented in Figure 22.

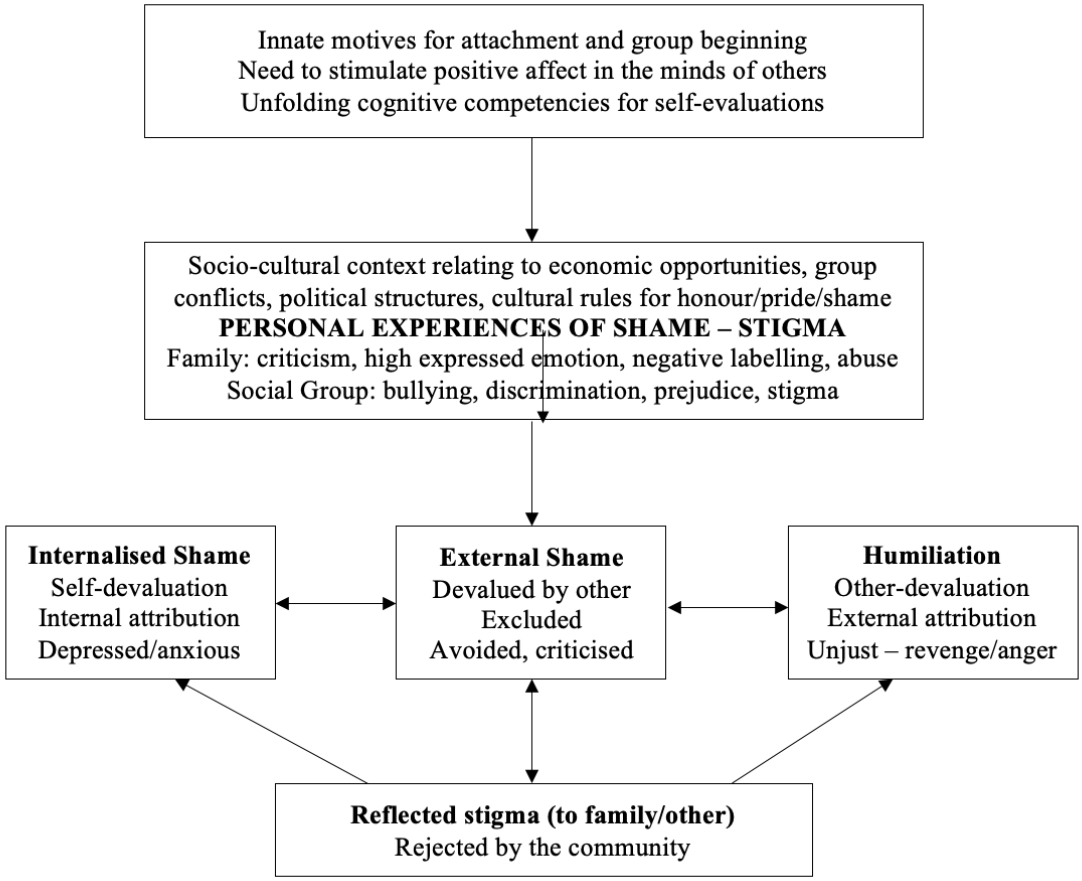


Figure 22: An evolutionary and biopsychosocial model of shame (Gilbert, 2010a).

Summary

This part of the chapter has focused on introducing and critiquing a range of psychological theories and models as they apply to HIV anxiety among GBM. It is argued that the minority stress theory and internalised homophobia may increase the risk of GBM developing anxiety disorders, such as HIV anxiety. Models derived from cognitive-behavioural therapy, as well the evolutionary and biopsychosocial model of shame, help form our conceptualisation of HIV anxiety among GBM. The next and final part of this chapter will frame the empirical study.

Framing the Current Study

Problem Statement

HIV anxiety is most commonly conceputalised as 'health anxiety' (Margetts, 2010), withn a cognitive-behavioural framework. Clinicially, this has resulted in clincians routinely operationalising the associated diagnostic labels, such as illness anxiety disorder (APA; 2013) and hypochondriasis (WHO, 2004), to categorise the distress these people present with. Furthermore, in accordance with the dominant evidence-base, cognitive behavioural therapy is recommended as a first-line intervention, which in England is primarily delivered within primary care services, such as IAPT (National Collaboration Centre for Mental Health, 2021). Despite their dominance, these diagnostic constructs and corresponding interventions may not capute the experiences of GBM who present with HIV anxiety.

According to the CBT model of health anxiety (Salkovskis, Warwick, & Deacle, 2003) the use of PrEP could be conceptualised as a safety behaviour. Safety behaviours include actions designed to detect a perceived impending threat, avoid it entirely, or endure it when avoidance is not an option (Helbeig- Lang & Petermann, 2010). Although the use of safety behaviours in the presence of actual threat is essential for survival, excessive and inflexible use of safety behaviours has been observed to maintain anxiety disorder symptoms (Salkovskis, 1991).

Measuring change in sexual behaviour after commencing PrEP is a focus of many studies in the light of concerns that PrEP use may result in shifts towards more risky sexual behaviours – "risk compensation" (Blumenthal & Haubrich, 2014). GBM who are using PrEP may compensate for the protection afforded against HIV by having more CAI (Traegar et al., 2018). There may also be undocumented psychological distress associated with sexually transmitted infection diagnosis, especially in the context of those GBM who have HIV anxiety.

It is evident that PrEP may have a range of psychological and psychosexual benefits. However, this has been an under-studied area and the research to date has primarily focused on acceptability, adherence, and risk compensation. Furthermore, the evidence of psychological and psychosexual gains has exclusively involved those who were eligible for PrEP, thus considered high-risk. To date there have been no studies that have looked at the experiences of low risk GBM, with HIV anxiety.

Aims

The aim of this study is to explore the experiences of GBM, who started using PrEP, despite not engaging in CAI (therefore deemed low risk). More specifically, the study will recruit those GBM who have experienced HIV anxiety and this experience meets the diagnostic criteria for illness anxiety disorder.

Research Questions

1. How does HIV anxiety develop and manifest in these GBM?
2. What motivates HIV anxious GBM to initiate PrEP?
3. How do HIV anxious GBM make decisions around initiation of PrEP?
4. What impact does PrEP use have on their experience of sex and sexual behaviour?
5. What impact does PrEP use have on experiences of anxiety?

CHAPTER TWO: METHOD

Chapter Overview

The current chapter describes the ontological and epistemological stance of the study, drawing on the philosophical background to the critical realist position. In defending a qualitative methodology, there is consideration of alternative positions and a discussion detailing the rationale for the undertaking of thematic analysis. Furthermore, the primary researcher considers his own position in relation to the development of the research topic through a self-reflexive account. The research procedure will also be outlined.

Philosophical Framework

Many of the research decision taken during research are influenced by the epistemological and ontological stance (Silverman, 2013), and it is therefore imperative that these are outlined. Furthermore, recognising my own personal subjectivity will in turn facilitate an awareness of the possible bias that may subsequently emerge, and thus increases the credibility of the research and promotes transparency of the research process and the methodological decisions which may influence the research outcomes (Frost et al., 2010). It is widely accepted that the philosophical framework should firstly consider the ontological stance, which will then aid the adoption of an epistemological stance, and in turn influence the selected research method.

Ontology

Ontology is defined as "a concept concerned with the existence of, and relationship between, different aspects of society such as social actors, cultural norms and social structures…. Ontological issues are concerned with questions pertaining to the kinds of things that exist within society" (SAGE, 2006). Ormston et al. (2014) states that ontology concerns

the question "whether or not there is a social reality that exists independently from human conceptions and interpretations and closely related to this, whether there is a shared social reality or only multiple, context-specific ones" (p.4). Succinctly, Guba & Lincoln (1994) state that the ontological position is rooted in philosophy and thought about in terms of "the form and shape of reality". Various ontological theories exist, and these are best conceptualised as being positioned on a continuum, with realism and relativism at either end.

Realism asserts that the worlds is separate from human interpretation and therefore objective measurement of reality is possible (Blaikie, 2007). Relativism suggests that reality is a finite subjective experience (Denzin & Lincoln, 2005) and beyond our cognitions there is nothing in existence. Reality is therefore not distinguishable from the subjective experience of it, from a relativist perspective (Guba & Lincoln, 2005). A realist ontology is reflected in the significant body of quantitative research regarding the efficacy of PrEP, which broadly suggests that some quantifiable realities are known and measurable. Notably, the significant reduction in HIV incidence among PrEP-using GBM reflects a known reality that exists as quantitative data. There may be different explanations for this reality and multiple means of measurement of the data, but it has nevertheless existed in empirical research over the last decade. A relativist ontology may be demonstrated by the experiences of PrEP use, insofar as research has consistently concluded that these are relative to the individuals and contexts.

Epistemology

Following from the ontological assumptions regarding the nature of reality, epistemology refers to how knowledge about reality is learned (Blaikie, 2007). There are two main epistemological positions: interpretivism and positivism (Ormston et al., 2014). Positivism asserts that valid knowledge is obtained through the application of scientific methods. In turn, it is therefore possible to reveal the single 'truth' (Denzin and Lincoln,

2011). Another feature of this position is that there is a dualistic belief that there is no influence between the research and the participant(s) (Scotland, 2012). Conversely, interpretivism rejects that the concept that knowledge is an objective account of reality. Therefore, knowledge is constructed thorough specific social and cultural contexts and that there are multiple knowledges with are subject to change over time (Patton, 2015). A positivist epistemology reflects the way in which knowledge regarding the efficacy of PrEP is acquired (i.e., through statistical analyses of numerical data). An interpretivist epistemology relates the way experiences of PrEP use are learned about, which is to say, through the interpretation of accounts of people who are using PrEP. The experiences are constructed not only by the participant but also the research; together, they create a coherent account.

Methodology

The ontological and epistemological position subsequently informs the selection of the methodology. Silverman (1993) defines methodology as the general strategy that is adopted by the researcher to investigate the topic of interest. Crudely, a quantitative methodology is usually rooted in a positivist paradigm and is rigid in approach, such as empirical measurements in the context of manipulating conditions. Research utilising this methodology is often hypothesis-driven and aimed at testing these through a controlled, logical, and structured approach (Krauss, 2005). Furthermore, there is also an explicit assertion that the researcher is independent from the phenomenon under scrutiny (Hudson and Ozanne, 1988).

Conversely, research that is rooted in an interpretative paradigm almost exclusively uses a qualitative methodology. The aim of interpretivist research is to understand, interpret and capture meanings attributed to subjective human experiences and participants' perceived realities (Black, 2006), which are intrinsically influenced by context and time (Hudson and Ozanne, 1988). The aim of the current research was to establish a greater understanding of the

experiences of HIV anxious GBM who PrEP. In this regard, it is not possible to ascertain the objective truth of the phenomenon, and it was therefore concluded that the most appropriate methodology was qualitative.

Self-Reflexivity

Reflexivity refers to the "analytic attention to the researcher's role in qualitative research" (Gouldner, 1971, p.16). It is both a concept and a process (Dowling, 2006). Considered as a concept, it refers to a certain level of consciousness. More specifically, reflexivity entails self-awareness (Lambert, Jomeen, & McSherry, 2010), which implies the researcher being active in the process. A central feature is the recognition that researchers are very much part of the social world that we study (Ackerly & True, 2010; Shaffir & Stebbins, 1991). As a process, reflexivity is introspection on the role of subjectivity in the research process. A continuous process of reflection by the researcher on their values (Parahoo, 2006) and of identifying, scrutinising, and making sense of how their "social background, location and assumptions affect their research practice" (Hesse-Biber, 2007, p. 17). Jootun et al. (2009) suggest that the key to reflexivity is "to make the relationship between and the influence of the researcher and the participants explicit" (p 45).

There is also evidence suggesting that self-reflexivity in the context of research adopting an interpretative paradigm, where is inevitable that a researcher will be unable to remain objective and outside the research subject (Palaganas, Sanches, Molintas, & Caricativo, 2017), can improve transparency and research quality (Lietz et al., 2006). As such, I have included a reflective account in this chapter. In this reflective account, I consider my personal experiences of both anxiety and HIV and how these have contributed to my 'truth'. Whist

some of the reflections are deeply personal, I consider these to be pertinent to achieving transparency with regards to my positioning in the current research.

I recall two experiences in my childhood where I was confronted with HIV. The first one was when I was 5 years old. I was at the park and picked up a can of Cola which was half empty and drank from it. My mum became hysterical. She snatched the can from me with such panic and shouted, "You could get AIDS!". I cried all the way home and was very unsettled and anxious. Now, with hindsight, this statement is both incorrect and rather cruel. It is therefore important to consider the prevailing context in which this statement was made.

I grew up in the late 1980s/early 1990's on a council estate on the periphery of Edinburgh – which at the time was dubbed the 'AIDS capital of Europe' due to a considerable outbreak of HIV among people who were injecting drugs – where drugs, addiction, and crime were commonplace. My mum's partner had recently died of cancer, and she was also battling with her own mental health. She had severe health anxiety, and this resulted in visiting (and battling!) her GP daily, often with my brother and I with her. In line with common practice at the time, she was prescribed benzodiazepines. Despite a short spell of remittance, she rapidly became addicted to these and would frequently overdose. Her distress worsened and she had a psychiatric nurse who visited her at home. I grow up in a very anxious environment and, despite my age, developed quite a sophisticated understanding of anxiety.

The second of time was when my mum introduced me to one of her childhood friends in a pub, when I was 8. The partner of my mum's friend was there too, and I remember my mum referring to him as a "junkie" and that he had "AIDS" – although derogatory, this language was commonplace during my childhood. I only ever met him a handful of times, but I remember him vividly. He was gaunt and his face dotted with sores. His arms were frail and covered in track marks from injecting heroin. He later died from HIV in the late 1990's. I recall my mum conversing with another friend and anxiously speculating about her childhood

friend perhaps “catching it” from her late partner. HIV was scary during my childhood, and this was perhaps exacerbated by my mum’s mental health difficulties. The anxiety it created in those around me was palpable and, inevitably, contagious.

Fast-forward to when I started college. I had realised that I was gay but hadn’t told anyone. There were other people at college who were gay and out; they got a hard time from people. Some of them were referred to as “dirty poofs” and there were ‘jokes’ about them having “AIDS”. I then started to make the connection between being gay and HIV, which worried me. If I was gay, then that would mean I was going to get HIV? Instead of being proactive about this and seeking more information, I decided to ignore the worry and push it the back of my mind.

I then moved away for university. I started having relationships with men – due to my ignorance, I rarely used protection. I started to have friendships with other gay men and encountered conversations about HIV and was introduced to the routine of testing. I’m not sure why, but at that moment, I began to experience intense anxiety regarding HIV and was convinced that I was infected.

Things deteriorated, and I began behaving like my mum; I’d regularly attend the doctor anxiously about every ‘symptom’. I ended up having to start taking medication to manage my anxiety and dropped out of university. I could no longer concentrate and anxiety about HIV overtook my life. I stopped having sex completely for fear of passing it on. But I still wouldn’t test. It was just too anxiety provoking. What if I ended up looking like that man my mum introduced me to in the pub?

Eventually, I decided to test, and it was terrifying. It took nearly two weeks for the result to come back. I had to go into clinic and if the results were negative then the receptionist would tell me and if any of the tests were positive, I had to wait for the nurse. I arrived at the clinic before it opened and waited outside. A queue developed with all in the line looking

either anxious or ashamed (I was both!). I went to reception and my heart was pounding. She looked at the file and told me all my test results were fine. I left the clinic and felt an overwhelming sense of relief.

Now, you would be wrong if you thought was the end of it. Despite testing negative, all the cognitive and behaviour patterns I had developed that maintained my anxiety for all those months seemed to be ingrained in me. It was as if they had become habit. I continued medication for another year or so and wasn't well enough to go back to university. Eventually, I began to overcome the anxiety and re-applied to go back to university. Unfortunately, I had lost my place at university due to amount of time I had taken out and therefore had to change university.

Alongside studying, I got a job with a local HIV charity. One of the projects I worked on was setting up a rapid HIV testing service to various 'at risk' groups. After a few months of being there, I noticed many 'worried well' people coming through the door wanting these rapid tests for HIV. Hearing their stories reminded me of myself when I was in Aberdeen.

I enjoyed the job and was nearly ready to graduate. I decided that I wanted to pursue a career in sexual health and HIV. I started working in Birmingham and quickly earned a reputation for being 'good' with patients who were health anxious. I then moved to London to work in several central London clinics, where I was diagnosing large numbers of people with HIV and this quickly took its toll on me.

In a single day in 2014, I diagnosed 8 people with HIV; most were of a similar age to me, and all were gay men. Later that year, one of my colleagues said that he had calculated that between the four of us in our team we had diagnosed 1 in 6 of the UKs new HIV infections among gay men that year. In this 'toxic' environment, anxiety began to creep back in and whilst I was now a provider and not a consumer of both sexual health and mental health care, I was unable to contain my own distress. I had to go back on medication and started

psychotherapy. In psychotherapy, I spoke about my childhood and my experiences of anxiety, particularly health anxiety. I also spoke about my identify as a gay man and what I thought this meant. This was a very valuable experience and gave me a greater understanding of myself and the context in which I had lived.

I decided that I wanted to leave sexual health and pursue a career in clinical psychology. I completed a MSc in health psychology and began work as an assistant psychologist, where I undertook some CBT training. This gave me a framework to understand anxiety from a cognitive and behavioural perspective. I applied for clinical training and was accepted onto a training programme, where I currently work as a trainee clinical psychologist. As someone who has experienced HIV health anxiety, a gay man, and a provider of mental and sexual health care this has inevitably impacted my positioning in this research.

Research Paradigm

A research paradigm consists of ontological, epistemological, and methodological views held by the researcher (Denzin and Lincoln, 2011). The current research takes a critical realist approach, which is described as a bridge between a realist ontology and an interpretivist epistemology (Grix, 2019). Critical Realism makes a distinction between the 'real' world and the 'observable' world. The 'real' world exists independently from human perceptions, theories, and constructions; it is not observable. The world that we know and understand is a construction form our perspectives and experiences, through what is 'observable'. Therefore, critical realists assert that unobservable structures create observable events, and the social world can only be understood of people understand the structures that generate events. In this ontological domain, the purpose of science is to identify phenomena and develop agreement regarding the description of the whole from glimpses or partial fragments (Bergen, Wells, & Owen, 2010). A realist ontology is considered appropriate to the current research because it

is argued that PrEP use is a reality. An interpretivist epistemology is considered appropriate to the current research because the experiences of PrEP use and HIV anxiety are subjective constructions or interpretations from the participants and the researcher, rather than objective observations from the researcher alone.

Obtaining Data

The research question informs the methods of obtaining data to ensure that what is collected is relevant and useful in the pursuit of enabling understanding of the studied phenomenon. For the current study, it is argued that there are insufficient academic accounts of the experiences of HIV anxious GBM who are using PrEP that can be analysed in service of the research aims, therefore novel data is needed.

The most common method of data collection within social science research are semi-structured interviews (Briggs, 1986). This method is closely associated with interpretivist and constructionist epistemologies and reflects an ontological position that is concerned with people's knowledge, understandings, interpretations, experiences, and interactions (Lewis-Beck, Bryman, & Liao, 2004). The logic of semi-structured interviewing is to generate data interactively, and Steiner Kvale has described qualitative research interviews as "a construction of knowledge" (Kvale, 1996, p. 62). Semi-structured interviews are often guided by pre-determined topic guide, which are flexibly adhered to throughout the interview to give some containment over the trajectory of the interview, whilst also facilitating space to allow participants to provide new insights. This method of data collection has been selected as it aligned to generating rich data about the participants experiences of using PrEP. Furthermore, given that the topic could be considered sensitive by some and has the potential to illicit psychological distress, this method maintains confidentiality.

Focus groups have been used as an alternative to semi-structured interviews. Unlike semi-structured interviews, which usually involve only one researcher and one participant, focus groups facilitate the opportunity to gather data on interactions between the participants in attendance at the group. During focus groups, participants are actively encouraged to remark on one another's contributions and challenge comments and develop thoughts, which in turn can provide rich data in a less artificial de-contextualised setting (Wilkinson, 1999). Despite this, the use of focus groups in the current research was deemed inappropriate for the following reasons: (1) the topic guide covers sensitive issues such as psychosexual functioning and psychological wellbeing, which are deemed sensitive. In turn, discussion of sensitive topics in such a format may inhibit responses and reduce the quality of the data collected; (2) it would not be possible to assess whether participants meet the diagnostic criteria for Illness Anxiety Disorder in this context; and (3) focus groups do not allow for in-depth exploration of individual experiences, which is the focus of the current study.

Why Thematic Analysis

There are multiple different approaches to analysing qualitative data and each of these will be discussed in turn and their possible utility discussed in relation to the current study. Consequently, this will clarify the justification for the selection of thematic analysis in the current study. Starks and Trinidad (2007) state that the aims and research questions are central in determining the most appropriate method of data analysis.

Grounded Theory

GT is a research method that aims to generate theory (Glaser & Strauss, 1967), which is 'grounded' in the data that has been collected and analysed systematically (Denzin & Lincoln, 1994). Central to this method is the desire to uncover such things as social

relationships and behaviours of groups, known as social processes (Crooks, 2001). As this method is principally concerned with generating concepts and hypotheses through an inductive, and evolving process (Charmaz, 2000), this method is most appropriate for explorative research where theory can evolve from the data. Whilst there are several advantages of this method, there is a lack of consistency regarding how the method is employed (Barbour, 2001), which in turn can result in methodological fragilities (Potrata, 2010). I therefore concluded that this method was not appropriate for addressing the current research questions which focused on describing GBMs experience of PrEP in the context of HIV anxiety, rather than generating a new theoretical framework.

Interpretive Phenomenological Analysis

IPA (Smith, 1996) and aims to uncover what a lived experience means to the individual through a process of in-depth reflective enquiry. IPA draws heavily on phenomenology, with the purpose to return "to the things themselves" (Husserl, 2001, p168). There is also an acknowledgment in IPA that individuals are influenced by the worlds in which they live in and the experiences in which they encounter. Therefore, IPA is an interpretative process between both the researcher and the researched, where the participant makes sense of their experiences and the researcher attempts to make sense and interpret the participant's world (Smith et al., 2009). Some of the criticisms of IPA are that it lacks standardisation (Brocki & Wearden, 2006).

IPA was not considered an appropriate method as it aims to make sense of individuals experience by focusing on single cases, or a small group of homogenous individuals. In the current study, the participants were heterogenous (insofar as age, relationship status, and nationality). Furthermore, as the current research aimed to describe participants' experiences, rather than interpreting the meaning of their lived experiences, thematic analysis was ultimately considered to be the most suitable method of data analysis.

Thematic Analysis

Thematic analysis is popular and widely used in qualitative research (Roulston, 2001). It applies a systematic approach to identify, analyse, and report themes across a series of datasets from a homogenous sample (Braun & Clark, 2006). The flexibility offered by thematic analysis is unique in that is does not prescribe an allegiance with a specified theoretical framework, data collection method, or ontological and epistemological positions. As such, this method can be deployed in a range of methodologies to answer research questions. Whilst the method has widely accepted guidelines, developed by Braun and Clark (2006), the techniques require no specific training to use it. Furthermore, the intuitive nature of the method means that it highly accessible to researchers. Braun and Clark (2006) assert that thematic analysis produces detailed, rich, and complex data that exceeds mere description and interpreting of certain aspects of the studied phenomenon (Boyatzis, 1998). Joffle (2011) suggests that there is evidence to conclude that thematic analysis is a useful method to allow participants voices to be heard.

Thematic analysis was selected as the most appropriate method of analysis in the current study as it has utilised widely in relation to topics pertaining to individuals' experiences and perceptions of studied phenomenon (Braun & Clark, 2013, p44). A thematic analysis was suited to capture common themes on key areas such as motivation, psychological impact (e.g., anxiety), and psychosexual impact in those HIV anxious GBM who are using PrEP.

Design

Study Setting

The study was a multi-centre study based at two NHS Trusts in London: Collectively, these clinics see more than 300,000 attendances per year. The participating centres were selected due to their high volume of patient attendances; they all offered free PrEP monitoring

to those who were self-sourcing PrEP. Clinics in south east London serve an ethnically diverse population and it was therefore hoped that this would increase access and to underrepresented populations, such as those from the BAME community, and thus increase their recruitment.

Study Context: Healthcare setting and CBT paradigm

Although the current study acknowledges there are issues associated with using diagnostic labels, such as illness anxiety disorder (APA, 2013), to categorise HIV anxiety, and the CBT model of health anxiety (Warwick and Salkovskis, 1900) to conceptualise HIV anxiety, it is accepted that the diagnostic criteria of illness anxiety disorder is the most widely adopted in clinical practice and is the most aligned conceptualisation, compared to other diagnostic terms (i.e., hypochondriasis (WHO, 2013)). Given the dominance of illness anxiety disorder and the cognitive behavioural model in conceptualising HIV anxiety (albeit inadequately), in the current healthcare context those presenting with this phenomenon will be likely be recommended a treatment that corresponds with these conceptulisations, which is a course of cognitive behavioural therapy, usually delivered in a primary care setting (e.g., within Increasing Access to Psychological Therapies (IAPT) services.

As a consequence of the prevailing healthcare context, the current study has opted to use the illness anxiety disorder critiera to screen participants in the study, and adopt a cognitive behavioural framework in exploring their experiences.

Research Procedure

Stage 1: Promotion of research. I attended the recruiting clinics to introduce the research and promote the referral of potential participants. I provided a short presentation to clinical staff on the background of the study, aims, the inclusion and exclusion criteria, referral process, and requirements of participants. Study materials were also made available to clinicians, to increase their knowledge of the study

Stage 2: Recruitment. Figure 23 provides an overview stage 2 of the research procedures. Eligible participants were identified during routine sexual health consultations with a clinician, who introduced the research and offered the participant information sheet (PIS; Appendix A) to potential participants. If participants were interested in learning more about the study or expressed a desire to participant, the clinician obtained consent to share their contact detail with me. Consent was documented in the patient's records. If they accepted, the contact details were sent via an NHS.net email account to ensure adherence to NHS policies and procedures. Alternatively, if the potential participant wanted more to discuss the research with other or were unsure, the were informed that they could contact the researcher via the contact details provided on the PIS.

In instances where potential participants were referred to participate or they made contact, I offered an opportunity for them to ask questions relating to the research. At this point, I ensured that participants met the study inclusion criteria and arranged an appointment at their clinic with me to obtain formal consent, complete demographic sheet and health anxiety inventory, and interviews. However, due to COVID-19, this process was moved online.

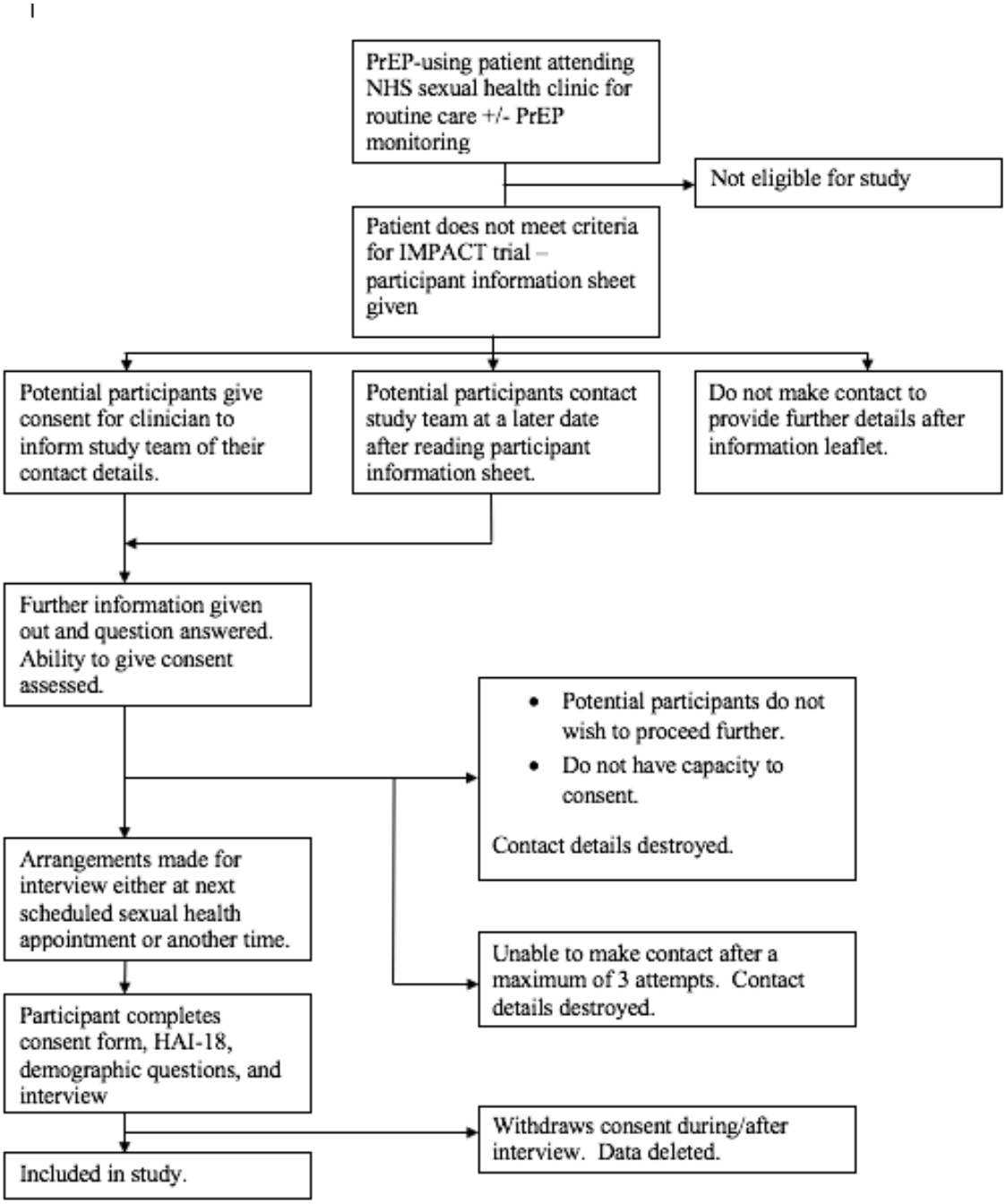


Figure 23. Study flow chart detailing research procedure for stages 2 and 3.

Stage 3: Data Collection. The recruitment and interviewing of participants occurred between February 2020 and December 2020. Informed consent was obtained from participants (Appendix B) prior to giving them the demographic sheet (Appendix D) and HAI-18 (Appendix C). Interviews were conducted in a private clinic room within the clinic to minimise

disruptions and to ensure confidentiality or online, using secure videoconferencing software. The interview began with building a rapport and introductions, the rest of the interview was guided by the interview topic guide (Appendix E). The interviews were audio recorded using a digital Dictaphone. After the interview, a de-brief took place if participants met the diagnostic criteria for Illness Anxiety Disorder, they were offered a referral for further psychological assessment and possible intervention, using their respective clinics established clinical pathway.

Stage 4: Data Analysis. Scores obtained on the HAI-18 and the clinical component of the interview were used to make a clinical decision if a participant met the diagnostic criteria for Illness Anxiety Disorder (either currently or historically), and participants were stratified accordingly. The current study only analysed those who met diagnostic criteria for illness anxiety disorder. Each of the interviews were transcribed by a professional transcriber and analysed using thematic analysis (Braun and Clark, 2006) by me (see Appendix F for a coded excerpt). During write-up, any epistemological assumptions that informed the analysis have been made explicit and a detailed account of the analytical process including justifications of any decisions are documented (Attride-Stirling, 2001).

Measures

Topic Guide

A topic guide (Appendix E) was developed to follow the aims of the research and to address the research questions. It was constructed in consultation with supervisors, and service users were involved in reviewing the topic guide to ensure the terminology was accessible and the tone was respectful. It is essential that topic guides are well-designed as poorly designed topic guides can potentially restrict the exploratory and reflective nature of qualitative research (Ritchie & Lewis, 2003). The topic guide covered 5 main areas: (1) motivations for initiating

PrEP; (2) HIV risk perception; (3) the psychological and psychosexual impact of using PrEP; and (4) a clinical interview relating to Illness Anxiety Disorder (see Table 6).

Clinical Interview

Included in the interviews were a clinical interview to ascertain the presence (current or historical) of symptoms of Illness Anxiety Disorder as set out in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V; APA, 2013). Table 6 below details the specific diagnostic criteria.

Table 6

Illness Anxiety Disorder 300.7 (F45.21)
Diagnostic Criteria
A. Preoccupation with having or acquiring a serious illness.
B. Somatic symptoms are not present or, if present, are only mild in intensity. If another medical condition is present or there is a high risk for developing a medical condition (e.g., strong family history is present), the preoccupation is clearly excessive or disproportionate.
C. There is a high level of anxiety about health, and the individual is easily alarmed about personal health status.
D. The individual performs excessive health-related behaviours (e.g., repeatedly checks his or her body for signs of illness) or exhibits maladaptive avoidance (e.g., avoids doctor appointments and hospitals).
E. Illness preoccupation has been present for at least 6 months, but the specific illness that is feared may change over that period of time.
F. The illness-related preoccupation is not better explained by another mental disorder, such as somatic symptom disorder, panic disorder, generalised anxiety disorder, body dysmorphic disorder, obsessive-compulsive disorder, or delusional disorder, somatic type.
Specify whether:

Care-seeking type: Medical care, including physician visits or undergoing tests and procedures, is frequently used.
Care-avoidant type: Medical care is rarely used.

Illness Anxiety Disorder classification and diagnostic criteria as per Diagnostic Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; APA, 2013)

Health Anxiety Inventory

The Health Anxiety Inventory (HAI-18; Salkovskis et al., 2002) was used to measure levels of health anxiety and was used in conjunction with the clinical interview to make a clinical judgement whether participants met the diagnostic criteria for Illness Anxiety Disorder. The HAI-18 is an 18-item self-reported questionnaire, which measures cognitive factors associated with health anxiety. Items on the HAI-18 are rated on a 4-point Likert Scale with higher scores reflecting higher levels of health anxiety. Previous literature has found mean scores of 37.9 (±6.8) to reflect populations with clinical levels of health anxiety. The HAI-18

has been shown to be a valid and reliable scale (r = 0.90) for the assessment of health anxiety (Salkovskis et al. 2002).

Data Analysis

Following each interview, I wrote reflections of the interview, with particular emphasis on identifying possible areas of bias. In turn, this facilitated increased transparency in allowing others to evaluate the extent to which biases may have impacted data collection and subsequent analysis. The analytic process followed the six-phased approach set out by Braun and Clark (2006). Figure 24 is a diagrammatic representation of the process. I adopted an inductive, bottom-up approach to thematic analysis. In doing so, I established explicit links between the raw data collected and the research aims and was able to summarise extensive data within a concise format (Braun and Clarke, 2006). This approach is compatible within an interpretivist paradigm (Cohen et al., 2007).

Thematic Analysis

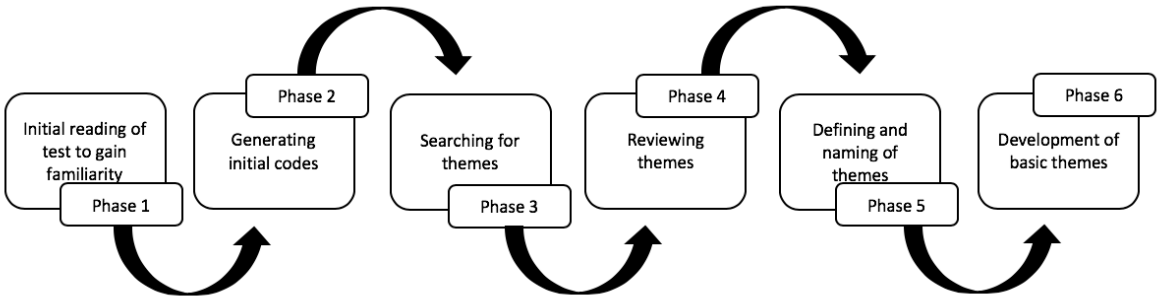


Figure 24. Braun & Clarke's (2006) six-phased approach to thematic analysis

Phase 1: Familiarisation with the data. This stage started through active reading and re-reading of the transcripts. It also involved making notes of any initial thoughts or points of interest.

Phase 2: Generating codes. Based on semantics and latent level readings of the data, the initial ideas generated from phase 1 in conjunction with the data to develop initial codes.

MAXQDA was used as a tool to code the extracts manually and collate the data pertaining to each code. Guided by the study aims and research questions, reading the data was done three times to determine the potential relevance of codes.

Phase 3: Searching for themes. This phase involved reviewing the codes compiled to identify similar concepts across the data set, and then clustering the codes into potential initial themes.

Phase 4: Reviewing themes. Themes were reviewed by checking the coded data extracts and examining whether each theme was supported by coherent and relevant data. This process also involved discussion the initial themes and subthemes (and their relevant codes) with the research supervisory team, to provide verification of the representativeness of the codes in the themes. Furthermore, the themes were then reviewed in relation to the dataset in its entirety to prevent overlooking any themes, ensure that the identified themes captured meaning across the dataset, and that the identified themes were meaningful in relation to the research questions.

Phase 5: Defining and naming themes. Themes were defined by checking relevant extracts and examining whether the essence of each theme had been captured. The themes and extracts were then discussed with the research supervisory team to assess the utility of the findings. Subsequently, the themes were organised into domains (which broadly corresponded with the research questions).

Phase 6: Writing the report. The final phase of analysis involved conveying the outcome of the analysis in a coherent and conceivable way. Each theme and subtheme are evidenced with appropriate extracts from the dataset, which are particularly vivid. In turn, the results chapter includes an analytic narrative that conveys an argument in relation to the research questions.

Participants and sampling method.

Research that utilises an interpretivist approach often uses purposive sampling when identifying and selecting potential participants (Creswell, 1998). Specifically, this method is used to identify and select those participants who meet pre-defined characteristics or knowledge relating to the subject of interest who are able and willing to participate (Cresswell & Piano Clark, 2011).

Inclusion and exclusion criteria were established after a thorough review of the literature and a discussion with a HIV physician. All patients attending one of the recruitment site clinics considered to be low risk for HIV infection *prior* to commencing PrEP were eligible to participant. Once a patient expressed an interest in participating in the study, the clinician would forward their details to the Chief Investigator, who would screen their eligibility to participate against inclusion and exclusion criteria, taking into consideration their capacity to consent.

Inclusion Criteria

1. Assigned a male gender at birth.
2. Self-identify as gay or bisexual.
3. Registered and receiving care pertaining to their use of PrEP at one of the study sites.
4. Aged 18 years or older.
5. Currently using PrEP either daily or event-based dosing for at least 90 days.
6. Prior to using PrEP did not have condomless anal sex in the preceding 90 days.
7. Negative HIV serology in the past 90 days.
8. English speaking.

9. Met the diagnostic criteria for Illness Anxiety Disorder, based on current or historical symptoms. **For this study only*

Exclusion Criteria

1. Deemed by their clinician or the research to be unable to provide informed consent.

Sample Size

A sample of 22 PrEP using GBM were stratified to one of two groups: (1) Those who meet the diagnostic criteria for Illness Anxiety Disorder (n=10); and (2) those who do not meet the diagnostic criteria for Illness Anxiety Disorder (n=12). Terry et al. (2017) recommends a range of 6-15 participants for doctoral-level research, therefore 10 individual participants in each group is considered an acceptable sample size. Furthermore, a total of twenty was an agreed sample size based the capacity and capability assessment carried out at each NHS Trust. Demographics for the participants included in this study are presented in Table 7.

Table 7

Sample characteristic

Participant Pseudonym	Age	Ethnicity	Sexual orientation	Marital status	Highest level of education	Occupation	PrEP regimen	Duration of PrEP use	PrEP source
Yusuf	33	White Turkish	Gay	Single	Postgraduate	Arts Production	Daily	9 months	Dean Street PrEP shop
Finn	29	White Irish	Gay	Single	Postgraduate	Management	Daily EBD	2 years 6 months	IMPACT trial
Dirk	23	White Dutch	Gay	Single	Undergraduate	Management	Daily	4 months	Dean Street PrEP shop
Nathan	31	White other	Gay	Single	Postgraduate	Student	Daily	1 year 3 months	Dean Street PrEP shop
Marcus	44	Indian	Gay	Single	Postgraduate	Management	EBD	2 years 4 months	IMPACT trial
Daniel	34	White English	Gay	Partnered	Postgraduate	Management	Daily	4 months	IMPACT trial
Jon	28	White English	Gay	Single	Postgraduate	Journalist	Daily	5 months	IMPACT trial
Hamish	57	White Scottish	Gay	Married	Postgraduate	Publisher	EBD	2 years 2 months	IMPACT trial
Mateo	28	White European	Gay	Single	Undergraduate	Civil Servant	Daily	5 years 2 months	IMPACT trial
Paulo	53	Mixed ethnic group	Gay	Partnered	Postgraduate	Nurse	EBD	4 years 9 months	IMPACT trial

Note. EBD = Event Based Dosing

Ethical Consideration

The British Psychological Society (BPS) Code of Ethics (2009; 2014) explicitly states the ethical standards expected in psychological research and by those who are professionally affiliated to the psychology profession. Throughout this research these standards have informed the study design and how it was conducted. The Code of Ethics (2009; 2014) was consistently adhered to, which related to the following areas.

Ethical Approval

After an ethical review by an NHS Research Ethics Committee (REC), approval was granted simultaneously by both the nominated REC (Appendix G) and Health Research Authority (HRA) (Appendix H). Subsequently, both NHS trusts' local Research and Development departments conducted a 'Capacity and Capability' assessment, as per HRA requirements, and granted the approvals for the research to commence in the designated sites (see Appendicies I and J).

Informed Consent

Potential participants were provided with a copy of the PIS. The PIS clearly stated the aim and purpose of the study and what participation involved. This was to support potential participants deciding whether to participate. Participants were given opportunities to ask questions prior to obtaining formal consent. Participants were informed that their participation was voluntary and could withdraw from the study at any stage, without giving a reason. However, it was made clear that if data had already been anonymised it would not be possible to retract data already collected and anonymised. Furthermore, it was made explicitly clear in the PIS and consent form that withdrawing from the study would in no way affect the care they were currently receiving at their NHS clinic.

Capacity was assessed by at the initial telephone contact and again prior to interview. This was achieved by exploring with participants their understanding of the purpose of the study and nature of the research, the potential benefits, and risks. This included how data will be handled and confidentiality. Furthermore, participants were asked if they had discussed their potential participation in the study with to establish whether there had been any element of coercion to take part.

Confidentiality

Participants were informed of the limits of confidentiality prior to the commencing the interview and that I would be duty bound to break this if they disclosed information that raised any safeguarding concerns for themselves or others (BPS, 2014). They were informed that in the first instance I would discuss with my supervisors and if they felt it necessary to escalate this then I would inform their clinician at the clinic, who would take appropriate action in line with their respective Trust's policies and procedures.

Anonymity

As the current study will collect data that is qualitative in nature, the results chapter (and subsequent publications) will include direct quotations from participants. Whilst every effort was made to protect anonymity by assigning each participant with a pseudonym, the risk remains that participants may be identified inadvertently (Larossa et al., 1981). Participants were made aware of this in the PIS and consent form. Steps were taken to minimise this by reminding participants to refrain from identifiable information that may lead to their anonymity being compromised.

Data Storage

The study was adhered to the Data Protection Act (2018). The audio recordings were encrypted and kept under password on a University server for a period of 12 months before being destroyed. Participants were each allocated a unique participant ID, with the ID key being kept on an NHS server and password protected. The participant ID was used in all study documents in place of identifiable information. These study documents were kept in a locked drawer in at an NHS clinic. A copy of the completed consent form was stored in the participants medical records for a period defined by the Trust operating the clinic where the participant attended. In line with the Data Protection Act (2018), participants were informed of data storage arrangements in relation to this study and that their transcribed data will be retained securely by the University of Essex for a period of 5 years after which it would be destroyed.

Psychological Distress

As participants were speaking about psychological issues related to their use of PrEP, there was potential for the interviews to elicit some psychological distress. Furthermore, an assessment of whether the participants met the diagnostic criteria for Illness Anxiety Disorder was undertaken. In the situations where the participant met diagnostic criteria, they were offered a referral for further psychological assessment. Care pathways existed in the participating clinics for such instances and the PIS also included information about where participants could access more support. Psychological distress was monitored throughout the interview, using my clinical skills.

PrEP Risk

Some participants were self-sourcing PrEP. Whilst it is accepted that the risks associated with using PrEP are sufficiently mitigated by accessing regular monitoring at a clinic, those who self-source PrEP may not be able to access the same level of monitoring as those in clinical trials. To mitigate this risk, participants were only recruited from NHS clinics that offered PrEP monitoring to those who were self-sourcing. The PIS included links to NHS-approved information accessible online to ensure participants were fully informed regarding the risks associated with PrEP. If participants proposed questions pertaining to clinical issues regarding PrEP during the interview, they were informed to seek advice from their clinician.

Quality Assurance

The quality of qualitative research has long been a focus of criticism from those positioned to a positivist position. More specifically, concepts central to positivism, such as reliability and validity, have proven very challenging to apply to qualitative research and have therefore led to some concluding that the methodology is inherently lacking in rigor (Shenton, 2004). In quantitative research, the notion of rigour is that an objective truth or reality is in existence (Burr, 2003) and this conflicts with research which utilises a qualitative paradigm, such as the current study. However, there is attempts in qualitative research on adoption of rigorous frameworks to mitigate poor quality (Frost and Bailey-Rodriguez, 2019). Some frameworks have attempted alignment with positivist criteria; however, it also argued that qualitative research should determine quality with concepts such as credibility, transferability, dependability, confirmability, and authenticity (Denzin and Lincoln, 2011). Table 8 includes evidence for how these criteria were met in the current study.

Table 8

Quality assurance criteria (as per Lincoln et al., 2011) and corresponding statement on how each criterion was satisfied

Criterion	Criterion Definition	How the criterion was satisfied
Credibility	The extent to which the research findings appropriately reflect the respective realities of the participants.	Analysis was grounded in participants verbatim experiences.
Transferability	Describes whether the research has applications outside of the study.	Details of research boundaries and context are provided, as well as participants' demographics.
Dependability	Describes how well a research may be audited by another researcher and refers to transparency.	A detailed research paradigm (including theoretical and philosophical assumptions) and operational implementation of the study is provided. Data collection was carried out consistently and interpretations are accompanied by verbatim extracts.
Confirmability	The concept of confirmability concerns whether reported findings reflect ideas and experiences within the data, or are unduly influenced by the preferences, characteristics, and biases of the researcher (Lincoln & Guba, 1985; Shenton, 2004).	Researcher's self-reflexive statement. Researcher engaged in clinical supervision throughout the process to monitor and mitigate their preconceived ideas and biases upon data collection and analysis.
Authenticity	The extent to which the researcher is emotionally candid.	Researcher's self-reflexive statement.

CHAPTER THREE: RESULTS

Chapter Overview

This chapter will present themes and subthemes from participants' data. Themes and subthemes are accompanied by interview extracts to facilitate understanding of the participants experiences of HIV anxiety and of using HIV PrEP. To protect anonymity and confidentiality, each participant has been allocated a pseudonym.

Interview order

Table 9 outlines the order research interviews were conducted, their duration, and participants' pseudonyms.

Table 9

Research interview order, duration and assigned pseudonym (N=10)

Interview Order	Assigned Pseudonym	Duration of Interview (min:s)
1	Yusuf	44:07
2	Finn	61:04
3	Dirk	53:49
4	Nathan	47:02
5	Marcus	47:01
6	Daniel	39:26
7	Jon	29:53
8	Hamish	43:25
9	Mateo	55:11
10	Paulo	47:37

Overview: Themes and Subthemes

Twenty-two themes and forty-nine accompanying subthemes were extracted, across five domains. Table 10 provides an overview of constructed themes and corresponding sub-themes.

Table 10

Constructed themes and sub-themes extracted from participants' data (N=10)

Domain	Theme	Sub-theme(s)
Sexual identity and stigma	Coming out	You're supposed to be straight If anyone else in this fucking family turns out to be gay, I'm going to kill them!
	Internalised homophobia	It's just a matter of time Everybody gay was promiscuous The good gays and the bad gays
	HIV stigma	Seriously? You caught HIV? Bitter about catching HIV
Attitudes towards, and relationship to, sex	It might kill me	
	I couldn't trust anybody	
	Casual sex	
HIV anxiety	It's part of me	Glass half-empty HIV is special I am the 0.0001% Destroyed my body
	HIV anxiety is omnipresent	It was a constant Everyone is in a high-risk category
	Misinterpreting my body	I had a tiny graze on my fingernail This is it!
	I'm scared because…	I'd be more concerned by the stigma I'm going to die
	I need to keep myself safe	Sex is on another land I'm more in control Reassurance
	HIV testing	Finding it very difficult to wait You've reset

Table 10 continued

Domain	Themes	Sub-theme(s)
Motivation for, and initiation of, PrEP	I can't tolerate the anxiety anymore	She saw how distraught I was I wasn't trusting condoms I need to enjoy myself before it's too late
	Responsibility	It's irresponsible for me to go and do that I've always been the serious one
	Accessibility	It's just another forestall Phoney medication
	Daily is best for me	Things are not always planned I know that … there is sex going on I'm very good at maintaining a routine
	EBD works best for me	
The experience and impact of PrEP	Facilitating a sexual life	Express myself sexually It's just pleasure I enjoy bottoming More prone to doing it
	Change in risk perception	I'm much freer now
	Disclosing I'm on PrEP	You're on PrEP and you're using condoms? I have to justify it It's good for people who have anxiety
	STIs	It's more of a chore It's like och It's a short-term issue
	Anxiety	Let my guard down I still have those anxieties There is HIV in my life now The next one in the line-up It's going to be taken away from me Bouts of anxiety I can kind of manage

Note. EBD = Event-Based Dosing; STIs = Sexually Transmitted Infections'

Supplementary data representation is presented in Figure X, which visually presents patterns of coded segments for each of the five domains (adapted from Verdielli & Scagnoli,

2013). The document portraits (Figure 25) demonstrate the prevalence of coded segments for each domain, as well as uncoded text, according to the colours assigned within the coding system. Codes relating to HIV anxiety and the experiences and impact of PrEP were most prevalently applied. Codes pertaining to sexual identity and stigma were least frequently applied.

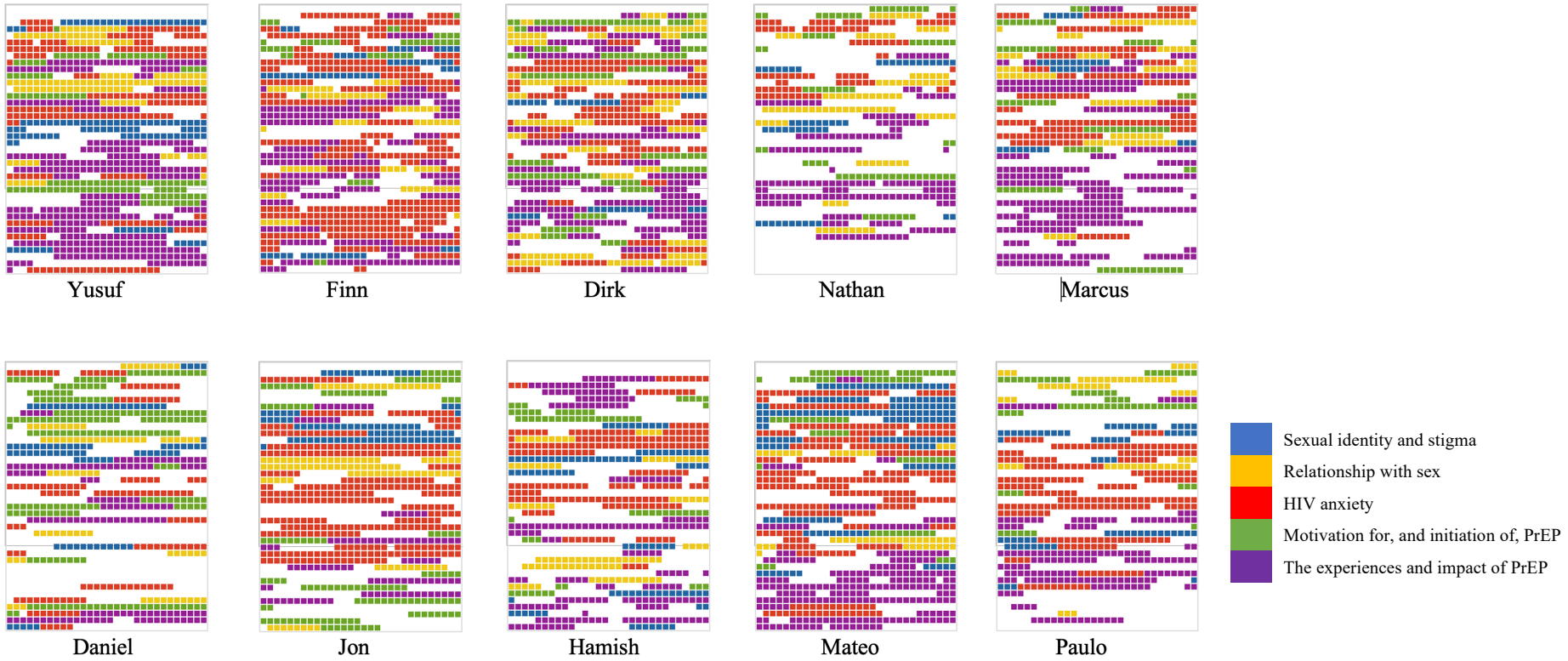


Figure 25: Document portraits for research interview transcripts, depicting the prevalence of coded segments associated with each overarching domain (N=10).

Domain One: Sexual Identity and Stigma

Three themes, and seven composite subthemes, were constructed summarising participants' experiences of their sexual identity and stigma.

Theme one: Coming out

Participants experiences of coming out were characterised by having to negotiate heteronormative experiences with their own sexual identity and dealing with the turbulence of coming to terms with and revealing their sexuality. Some participants consciously rejected their sexuality and attempted to assimilate themselves into heterosexual relationships.

You're supposed to be straight. Participants recalled growing up in cultures where being gay was not acknowledged and, at times, openly rejected. Yusuf explained that "According to … unfortunately in Muslim cultures, so I mean you can remember Ahmadinejad saying that there are no gay people in Iran, so because of that culture…" (para. 13). Heteronormative expectations can lead to life trajectories that are fundamentally incompatible to embracing their sexual identity. For example, Finn noted:

> "I think it comes from me being in Ireland and my Catholic up-brining and first of all you're supposed to be straight, you're supposed to have, get married, have kids, and that's the end all, whereas like… <chuckles> not really talked about the gay village kid that grows up in the city." (para. 179)

This lack of acknowledgement of difference in sexuality was evident in the sex education that participants received, which further alienated their sexual identities. Specifically, participants recalled the feeling of being 'othered' by the absence of talking about health gay sex and relationships. In turn, by reinforcing heteronormative narratives, the lack of acknowledgement of homosexuality led to further alientation.

If anyone else in this fucking family turns out to be gay, I'm going to kill them!

For some participants, the process of coming out was characterised by inner conflict and distress. Mateo remarked that:

> "I didn't fit in with the gays, because gays were openly gay and I wasn't prepared to associate with those people then, but I also didn't fit in with the straights. So, I had a really difficult time, and I went for psychological help, and I was diagnosed with something called avoidant personality disorder" (para. 28)

These experiences of inner conflict and distress contributed to difficulty in openly expressing their sexuality or coming out to their families. Daniel recalled feeling unable to come out due to fear of upsetting his family. Specifically, he said: "Well, remember what [my dad] said when my brother came out? He said, 'if anyone else in the fucking family turns out to be gay, I'm going to kill them'" (para. 38).

In response to their own discomfort with, and others' disapproval of, their sexual identity, some participants suppressed their sexuality and initially attempted to live as a heterosexual. Daniel explained that he "tried to be straight; I went on dates … I just wanted to please them, because I saw how badly that my parents took it" (para. 38). Fear impeded Paulo's willingness to accept his sexuality: "Well, sex… effectively, the first time I had sex, I was 23 … because I was so terrified and everything, so I had sex with girls, first" (para. 37).

Theme two: Internalised homophobia.

Societal messages that do not value homosexuality could lead to internal distress regarding participants' sexuality.

It's just a matter of time. Participants reported a perceived association between their sexuality and an inevitability of acquiring HIV. Mateo conveyed:

> "… I sort of saw it as some sort of divine retribution; if you mix with those kinds of people and you do those things, these are the natural consequences of your behaviour, and people will see you for piece of shit you are …" (Para. 22)

Bearing witness to other gay men succumbing to HIV perpetuated the sense of inevitability, even in the context of using condoms. For instance, Paulo recalled:

> "I used to ask to my friends on the beach in that time, saying, 'Who's gonna be the next one?' because you always … time to time we'd say, 'Oh, this person is positive now,' or say, 'Oh, now it's this person,' and then I remember to say with friends, I'd say, 'Sometimes I think that it's just a matter of time that one of us will become positive.' Including here in London, I said that in a conversation with friends, with closest friends, would say, 'Oh … sometimes I think, even used condoms, it's a matter of time that the group, or someone will become positive and then the other …'. (Para. 69)

Everybody gay was promiscuous. Societal messages around promiscuity among gay men are internalised by some. Daniel reflected on how a conversation with his mum led him to associate promiscuity and being gay:

> "…she would sort of like, 'Oh, my colleague, Danny, he's very– he's gay and he's got lots of friends, and he's promiscuous' and everything. So everything came to this whole thing that everybody gay was promiscuous. I was sort of like, 'I don't want to be that bunch,' because it would scare my mum." (Para. 71)

Mateo cited the national press as a source of his perception that gay men are promiscuous, stating that "it is a narrative that's out there, for the gays to get drunk or high and have bareback sex with strangers in a group context; this was in the national press" (Para. 65).

The good gays and the bad gays. Adoption of heteronormative behaviours and rejection of gay identity was associated with increased social rank and acceptability. Mateo suggested that:

> "…I think there's still a perception these days that there's the good gays and the bad gays; and the good gays assimilate in society and stuff, on a more heteronormative lifestyle, I suppose, so they just *happen* to be gay. I didn't have that reference back then, there was just normal people and … the gays, who weren't part of normal society." (Para. 26)

Theme three: HIV stigma.

HIV stigma was related to shame due to inferences made about how an individual acquires the infection. These inferences were perhaps a composite feature of internalised

homophobia, bourne out of their lack of internal and/or external acceptance and adjustment to their sexuality. Ironically (given the sense of inevitability some reported), there was also a belief that HIV was wholly avoidable and those gay men who did go on to acquire HIV were viewed as a failure in sone way. Marcus conveyed:

> "See, it's different than if it was a non-preventable disease, including like a COVID thing; it's like, that's so random, when you might catch something that you can't even control as much. Whereas this feels very controllable, so honestly, you kind of think, 'Seriously? You caught HIV? After all the education we have?' You know, that's the kind of mentality I had towards it …" (Para. 63)

A perception that some gay men who are infected with HIV may be motivated by their despair to infect those who are negative appeared to exacerbate HIV stigma. These beliefs mirror societal depictions of those with HIV in the media and and serve to increase participants risk perception of HIV in sexual situations. Mateo surmised that:

> "And the level of anxiety while having sex too, because I was thinking, 'What if … are they trying to,' that sort of thing. I also had this kind of belief that inevitably there would be some people who would be bitter about having contracted HIV and would want to give it to other people." (Para. 83)

Domain Two: Attitudes towards, and Relationship with, Sex.

Three themes were constructed summarising participants' relationship to sex.

Theme one: It might kill me

Sex between men is viewed as dangerous and has the potential to lead to serious consequences, even in the context of condoms. Finn explained that the increased prevalence of STIs among gay men leads to sex being viewed as inherently dangerous:

> "… because I think life in the gay community, we do have a lot more STD cases and it happens and a lot more my friends who are gay have caught STDs versus my straight friends who never have." (Para. 77).

Sex is viewed as dangerous and even with a condom, is not 'safe'. Hamish reflected that "because it wasn't 100%, so you'd always think, 'Well, maybe that was the time. You know, maybe the time the condom breaks, or you forget to use it or… the one time that you can get it from oral sex or even just touching." (Para. 46).

The consequence of sex on gay men's health is perceived as potentially fatal, due to the possibility of acquiring HIV infection, which in turn inflicts psychological distress. Yusuf thought that "having … seeing sex as a … doing this enjoyable activity, but it might kill me, every time. That was how it was seen by me. And seeing it like that, and it just really … it caused a lot of damage" (Para. 61).

Theme two: I couldn't trust anyone

Instances where partners have taken the condom off without consent have exacerbated lack of trust in future partners. Yusuf explained that he "always had this fear of HIV and it got worse through experience, through loss of trust in other people, because people lie" (Para. 17). Mateo recalled an incident with a partner which led him to be suspicious of future sexual partners:

> "[he] tried to take the condom off, without me noticing. So, that gave me a lot of anxiety in terms of, I couldn't really … I didn't really trust anyone in the first place, but this didn't help. I couldn't trust anyone sexually, so I always had to be in a position where I could be in control of … like, visual … I could visually see that no one was taking off the condom or sabotaging it." (Para. 79)

Negative experiences where partners have deliberately taken off the condom led to participants needing to be hypervigilant during sex. Yusuf recalled:

> "…the guy tried to take off the condom during sex, and I felt it on my feet and that sort of … I don't know, it didn't trigger but it made things much worse for me." (Para. 13)

Paulo reflected on his time as an HIV nurse and noticing that some patients on the ward had been infected by their partners, which left him feeling unsure of future sexual partners fidelity:

> "the stories I've been reading in notes of patients that got infected because the partner was cheating. But you know, you're not completely sure that your partner can't be cheating you; so, I have to risk, I just want to be happy." (Para. 37)

Stories in the media reporting on people being deliberately infected with HIV have also contributed to a narrative that sex is dangerous. Yusuf explained that:

> "Like last year, BBC for example had this media of this guy who was positive, and he was willingly making other people positive because he said it makes him feel powerful." (Para. 15).

Partners that are sourced using geospatial social networking applications (e.g., Grindr) are viewed as especially untrustworthy. Dirk recalled that he was "very worried about not being able to trust anyone, especially when meeting someone on an app" (Para. 55). Partners that use geospatial apps are viewed as more promiscuous. Daniel explained that:

> "It just made me anxious and clam up; I remember dating some people years and years ago, when I first came to London and it was the fact that you went on a date … <laughs> I mean this the hypocritical– the funny side, it's sort of, I would go onto Grindr to see afterwards if they'd gone online; sort of like, 'Oh that date was terrible,' they've gone straight back on to Grindr <laughs> at the end of the date." (Para. 38)

Theme three: Casual sex

Casual sex is perceived to be higher risk and can trigger anxiety. For instance, Dirk reflected:

> "I would feel a little bit dirty afterwards, not because I was ashamed of having sex, but just because I was like, 'I don't if I can trust this person, and whether this was the best idea. But I've done it now, so where do we take it from there?' There was a lot of anxiety, especially with strangers." (Para. 55)

Categorising casual sex as high risk and thus a trigger for anxiety can be a consequence of previous negative experiences with partners. Finn explained that "… I just

couldn't … 'cause that incident related to having sex with a one-night-stand partner, I just relate dramatic experiences to one-night-stands <laughs> so I couldn't really enjoy sex" (Para. 68). Even in the context of using condoms, casual sex can be perceived as risky: "… a one-night stand even if I've taken all the precautions, I still think the risk is there" (Finn, para. 68).

An association between causal sex and HIV can be instilled through others. For example, Daniel concluded that "… this probably stems back to when I first came out to my parents age of 21. They grew up in the era of AIDS and everything, the late eighties, and essentially, I got from them was, 'Don't be promiscuous'" (Para, 10).

Domain Three: HIV Anxiety

Six themes and fifteen sub-themes were constructed summarising participants experiences of HIV anxiety, prior to using PrEP.

Theme one: It's part of me

HIV anxiety was often considered to be intrinsically part of the individual. Finn stated "… if I could get a screwdriver and open up my brain it'd probably be just an absolute mess of different sort of shelving units with loads of different scenarios that'll work its way out, but it is what it is." (Para. 186). HIV anxiety can be made sense as a manifestation of other mental health difficulties. Yusuf concluded that "because of my obsessive-compulsive disorder, I was incredibly afraid of HIV" (Para. 12).

HIV anxiety also appeared to be an intrinstic component of participants personalities. Specifically, HIV anxiety is attributed to being pessimistic by nature. However, there were also instances where participants speculated that the anxiety was instilled in them from homophobic narratives of those around them.

HIV is special. HIV anxiety is considered distinctly different to other sources of anxiety, perhaps due to its pervasive nature and the omniprescence of HIV infection in their communities. Marcus noted that he was not generally anxious about his health:

> "… I used that word as a joke, but I'm not a hypochondriac in my regular health life, at all, I mean not really. But in this area, I seem to be risk-averse, quite risk-averse. So, it doesn't even matter if it's actually penetrative sex. (Para 21)

Marcus reflected that "as far as I can figure the HIV one has a special kind of like fear factor to it, versus everything else." (Para. 23). Participants described that even sexual acts considered low risk generated HIV anxiety. Furthermore, a discrepancy between acceptability of risk between HIV and other illnesses was noted. Hamish elaborated that:

> "Even though I could tell myself that rationally there was very little chance of catching it, considering what I'd done. Well, probably zero chance in most cases, but somehow, I always used to think, 'It could be this time,' 'You could be the 0.1%.' And somehow, 0.1% of catching HIV is a terrible thing, whereas 0.1% of catching any other <laughs> disease; you'd say, 'Oh! Well, no chance of that, is there?'" (Para. 46)

Participants appeared motivated to mitigate any potential risk where possible. For instance, Daniel recalled thinking "'What if, what if, what if', I'm always about trying to get to zero risk, or minimise it to the closest point to zero percent chance." (Para 10). Intolerance to any risk of HIV can lead to safety behaviours, such as repeated testing.

Destroyed my body. Subjectively, HIV anxiety can result in negative long-term consequences on health, which can persist even in the context of no longer experiencing acute anxiety. Finn said that "… it was horrible. My body wasn't the same after, and I just … I totally … destroyed my body in that sense." (Para. 39). Hamish reported that HIV anxiety impacted various domains in his life, not just his sexual behaviour: "…it affects all the other aspects of your life, as well. Yes, at times it did have an impact on my mental health, general health as well … and my confidence as well, I suppose." (Para. 20)

Theme two: HIV anxiety is omnipresent

The acuity of HIV anxiety is dynamic, with peaks and troughs of intensity but omnipresent background fear. This persistence is attributed by participants to a sence of inevitability, which appears to be cognitive feature of HIV anxiety, in becoming infected and their low threshold for perceiving risk. HIV anxiety is perceived to be a reality for gay men that must be managed to engage in sexual behaviour. For example, Paulo said: "… before the PrEP, you always have this question of the HIV back there in your mind, because this is our … is the reality. So, it was a constant situation that didn't disappear, (Para. 93)

Participants reported feeling a lack of control in their ability to remain HIV negative, despite being objectively low risk. This can lead to rumination about becoming infected with HIV and development of the belief that this is inevitable. For instance, Yusuf reflected on when he first moved to London: "I can't … that is … it's like entering the terror zone back then, in my mentality, it was a bit like entering the … walking on minefields." (Para. 19)

The perceived lack of control over maintaining their HIV negative status can result in a diminished locus of control. For instance, Paulo lost confidence in his ability to remain negative and thought he "tried to be careful … using condoms and everything. But at the same time, I thought it might be just a matter of time…" (Para. 69.)

Paradoxically, testing does not always reinforce that behaviours are not high risk through repeated negative results. Moreover, it can perpetuate a sense of inevitability through a perceived inertia towards changing sexual behaviours. Mateo reflected on his testing experience:

> "… after [testing] it was a relief, but it was also a bit of a curse, because then I sort of thought, 'Well, now I need to maintain it, and I haven't made any changes to my life, so it will happen'." (Para. 59)

Everyone is in a high-risk category. HIV anxiety is often frequently and repeatedly triggered, as well as maintained in the long-term, by the perception that sexual partners are

considered high risk based on their sexuality (irrespective of behaviour). There appears to be an inflated sense of risk associated with sexual partners. Ultimately, partners, especially casual partners, are deemed to be dangerous and vectors for HIV infection.

Theme three: Misinterpreting my body

In keeping with various cognitive-behavioural models of anxiety, HIV anxiety can lead to becoming preoccupied with the body and, crutially, interpreting bodily changes as evidence of HIV infection, when in fact they are benign or entirely normal. This is often triggered after sexual contact. Mateo said he was focused on his body to ensure he noticed changes:

"you can present the nodes, you can present the rashes; and of course, all the time you have to be … you used to looking your body, if you had symptoms and things like that, you know, the sarcomas and … yeah, for sure." (Para. 41).

I had a tiny graze on my fingernail. Hypervigilance for symptoms that may be suggestive of HIV infection can often be triggered after sexual contact. For example, Daniel recalled a pattern of anticipatory anxiety relating to the onset of seroconversion illness after having sexual contact with a sexual partner:

> "I would go on a date, we had sex and all the other stuff, and then I would sort of be clock-watching, 'Oh, it's been five days I'm fine, seven days, oh, I think I've got a tickle in the back of my throat,' or 'I think I'm coming down with a cold.' It was those sorts of things, or you end up psychologically making yourself think you're ill, when you're not. And I don't know why I did it …"

Hypervigilance for symptoms that are suggestive of HIV infection is not confined to participants' own bodies but could also include observing others (especially sexual partners) for signs and symptoms of HIV infection. For example, Mateo talks reflected on his tendency to look for signs of ARV use in others, such as lipodystrophy and lipoatrophy:

> "I think I've repressed this thought, when I was out in a gay bar, or I met anyone who was gay, I would look at them really closely, to see any signs of antiretroviral use. As I'm sure you know that it's only certain types of ARVs, people who have been on

> them for a very long time have certain physical signs, which if you looked really closely, sometimes you can see. But they *may* not be because of HIV, they may be related to their genetics, or their diets." (Para. 51)

Paulo also reported looking for physical symptoms that might be associated with behaviours considered to increase HIV risk to risk-assess potential sexual partners. For example:

> "… what people in gyms term 'bacne', sort of like a rash in the back area, which I think is more due to steroids than anything else; I've never done them, so I wouldn't know. I sort of connected it with a certain lifestyle that some people follow in London, where you go to the gym and then go on those parties that go on for days and have unprotected sex with as many people as you can find, who are doing a drug binge for …" (Para. 53)

Body scanning after sexual contact also has the potential to induce anxiety and may not always result in reassurance, despite that being that being one of the motivators. Hamish told of scanning his body for entry routes for HIV after having sexual contact with a partner: "… even just touching, and I think … I remember thinking, 'Ooh, I had a tiny graze on my fingernail or something, that could have been a chance to get HIV'." (Para. 46). Reassurance from others can have a limited impact in reducing anxiety. For instance, Jon observed:

> "That's definitely been a contributing factor. So yeah … well, I think I've always been very much symptom-conscious anyway, which, my friends will go, 'Why are you panicked?' 'Why are you worried about it?' 'You've always had safe sex,' but it's a case of … I don't know, I am quite symptom-conscious really." (Para. 43)

This is it! Distress associated with the appraisal that symptoms were a result of HIV infection is common, especially in the context of seroconversion. Paulo recalled "… when you have fever, you always have to think, lots of things … in that time I remember being very conscious, and think of, 'That could be HIV'" (Para. 47). This anxiety can sometimes build up in between HIV tests. For example, Mateo said:

> "What I … had was anxiety building up during that time, not just health anx– I saw it as health anxiety; everything I saw was a sign of damage to the immune system. You know, a cold and I was thinking, 'Oh God! This is it! I'm gonna have to go into hospital and they'll find out.'" (Para. 28)

Theme four: I'm scared because…

There is variance in the core fears that perpetuate HIV anxiety. Specifically, although some participants were fearful of the potential impact on their physical health (which is consistent with cognitive behavioural models of health anxiety), and even death, others were fearful of the perceived stigma and social consequences of an HIV infection (which appears more consistent with cognitive behavioural models of obsessive-compulsive disorder and also the biopsychosocial model of shame).

I'd be more concerned about the stigma. HIV anxiety cognitions can be less about the infection itself and more about the perceived social consequences of being HIV positive. Finn said: "I don't think I'm necessarily overly anxious … I think if I caught HIV tomorrow, I think I'd be more concerned about the stigma attached to it rather than the disease itself, and that's being totally honest with you." (Para. 165). In the context of anxiety relating to how others may negatively view them if they were to acquire HIV, shame acts as a feeder for the anxiety. Furthermore, HIV anxiety in this context may be conceputalised as protective, insofar it keeps then safe (i.e., HIV negative) and therefore protects them from the shameful experience (i.e., becoming HIV positive).

Stigma associated with being HIV positive was thought to be related to others viewing them as promiscuous if they were to test positive. Jon explained that: "I think with a lot of people, there's still that kinda cliché around HIV and promiscuity. That I suppose I would have shame being associated with, although that's not always the case and people can transmit HIV in all sorts of ways" (Para. 23). HIV anxiety in the context of being fearful of loss of social rank appears to be a manifestation of homophobia, both externally (via previous experiences and societal narratives) and internally (via their own negative beliefs about homosexuality and HIV). This can be illustrated in perceived differences between how heterosexual and gay people would respond when learning that someone is HIV positive.

Mateo thought that there may be a difference between how gay and straight people may think or respond when finding out someone is HIV positive:

> "I think still … these days you go to a straight person and I think if you ask them what's the first thing that comes to your mind if told you they were HIV-positive, it would probably be something like disgust or fear, rather than surprise or compassion, or anything else …" (Para. 29)

It was perceived that an HIV infection may result in social isolation and being ostracised by those in their lives. Finn reflected on his fear of his relationships breaking down:

> When I was catastrophizing that, when I was having a breakdown, it wasn't my compromised immune system. It was, when I think back it was more about what would people think. I felt like I'd never have a boyfriend, who'd want me, my mum and dad would disown me, other such thoughts, which is completely untrue. However, at that moment in time …" (Para. 166)

The fear of stigma can be so pronounced that it can prompt suicidal thoughts at the thought of being HIV positive. For instance, Mateo reflected on his decision to not collect the results of his first ever HIV test:

> "So, I never collected the results. Back then … I think my perception has changed now, but I remember how I saw it then, it was … for me it would have been preferable to be dead, than to be living with HIV, because of the huge, *huge* stigma that it had." (Para. 22)

I'm going to die. Despite drastic improvements in the prognosis associated with HIV, the impact of the early years of the epidemic has had a lasting impression. There appears to be a legacy effect. The fear of death makes HIV different from other sexually transmitted infections. Marcus said "and then, also … well, there's the whole … the fact that it likes death, right? That's what makes it different to the other ones" (Para. 27). Daniel commented that notoriety of HIV being associated with death is linked to his experience of HIV anxiety: "it's been because the fear of the HIV is that one that, 'Oh, well, that's a kil–' you know, other people's mindsets, 'Oh, if I've got HIV, I'm going to get AIDS, I'm going to die', blah-blah" (Para. 87).

Theme five: I need to keep myself safe.

Motivation for taking PrEP stems from a desire to safeguard their HIV negative status.

Sex is on another land. Avoiding having any sexual contact with other people can be used as a strategy to manage HIV anxiety. For instance, Yusuf recalled: "Then the first three years [in London] I was also celibate … I read on the internet that London is the HIV capital of Europe, and one out of seven gay men are positive." (Para. 19)

Although for some this strategy eliminates their subjective risk of becoming HIV positive, it does not fully abate anxiety in others. For example, Yusuf said that despite "being celibate for five years" (Para. 17), "I felt … again I was aware that if I continue to be celibate, I'm not going to, most probably I'm not going to get, but …" (Para. 35). Avoiding sex completely may adversely indirectly impact self-care due to low self-esteem and a sense of hopelessness. For instance, Yusuf elaborated:

> "… because sex was not a potential thing for me anymore, there was no reason for me to look after myself … and I was so used to the practice of … on the street I see this guy, oh he's very handsome, and that is it – the potential of that following into anything else was dead to me. So, it sort of … I felt like sex is on another land and I am on this other land. So, there is no reason for me to be sexually attractive." (Para. 66)

Setting rules around what sexual activities are acceptable, in terms of the level of anxiety elicited, can help avoid becoming HIV anxious after sexual contact with a partner(s). Hamish for instance, said: "So yes, what I would allow myself would be basically mutual masturbation, and anything else would be a source of worry; oral sex, fingering, all that kind of thing …" (Para. 88). However, due to the fluctuating nature of HIV anxiety, and thus changes in cognitive patterns (i.e., decision making), these boundaries are unrealistic and breached, which can lead to self-depricating thoughts and increased distress.

HIV anxiety may lead to rumination before, after and during sex, which can sexually inhibit; this in turn reduces sexual satisfaction. For instance, Finn said:

> "I know it sounds really stupid, it's the last think you'd think you'd be thinking about after engaging in sex, but I always had it there and I couldn't get rid of that, and it would make me be a lot more reserved when it comes to sex or just not fully engaged in that moment. I was more, my mind was elsewhere even though my body was somewhere else." (Para. 78)

I'm more in control. Seropositioning can afford an increased sense of control. Finn reflected that he is normally the insertive partner during anal sex as this gives him a greater sense of control over the situation and therefore helps reduce anxiety: "I just feel like I'm more in control of the situation when I'm topping because I'm putting on the condom and I'm kind of more …" (Para. 88).

Being the receptive partner during anal sex can give rise to anxiety about giving the other partner(s) more control during the sex, which increases a sense of risk. Increased control during sex can extinguish anxieties that the other partner(s) may deliberately tamper or remove the condom. Mateo said: "I couldn't trust anyone sexually, so I always had to be in a position where I could be in control of … like, visually … I could visually see that no one was taking off the condom or sabotaging it." (Para. 79).

Reassurance. Access to PEP can be problematic for people with HIV anxiety when the subjective risk does not correspond with the objective risk. This can be perceived as unfair as it does not factor in anxiety. Mateo, for example, said of access to PEP in the UK NHS:

> "The way I saw it is, there is a risk, more than a theoretical one. It may be low, so what they're going to be doing is … essentially, you're rationing PEP, because it's very expensive for a publicly funded health system …I felt that in this situation, I was entitled to accept … to decide what the benefit was, and for me, the benefit was more than producing a low chance." (Para. 69)

Commencing PEP may have a paradoxical effect in the context of HIV anxiety; insofar as it can increase anxiety whilst taking the treatment but is also sought out during

periods of anxiety after engaging in a perceived risk behaviour. The pursuit of PEP in the context of low-risk situations can lead to a person providing the health care professional with an inaccurate history, to inflate the level of risk, to ensure that they access the treatment. For example, Mateo said: "I had one course once and then that kind of increased the anxiety, so then I would find myself lying; I sort of knew what the criteria were for PEP, which boxes I had to tick …to ensure that I would be prescribed PEP when *I* felt I needed it." (Para. 39)

Seeking reassurance can temporarily alleviate anxiety at times of acute distress. For instance, Finn said "obviously the team here are great and calmed me down and did everything they could to reassure me and get me out of that period, but it definitely wasn't a great time" (Para. 35). Similarly, Dirk described seeking reassurance from a health care professional at the sexual health clinic after a low-risk sexual contact:

> "Oral and … there was contact, and it went in like, once accidentally, which [the clinic] then reassured me that that was very unlikely to have happened anyway. And he said that he was on successful treatment for like, 22 years, which is a long time." (Para. 53)

Despite inherent difficulties with reassurance, it can be seen as being responsible and helps maintain health by being 'safe'. For instance, Dirk said: "…but I do, as soon as something feels out of the ordinary, get worried that it could be something really serious and I'd rather be safe than sorry, by knowing." (Para. 47)

Theme six: HIV testing

Testing for HIV can be traumatising and trigger memories of the early days of the epidemic in their communities. Paulo reflected on his experience of HIV testing: "I … it has rescued all those feelings that I have in the late eighties, and the beginning of nineties, that's terror of to be the next one; that came out again." (Para. 55)

Finding it difficult to wait. The latency between having a perceived risk and being able to have a valid HIV test is associated with increased anxiety, which can impede functioning. For instance, Hamish reflected on the impact of having to wait to be out of the window period: "…I would start to get quite anxious and really worried and … finding it very difficult to wait those three months, the window to get tested." (Para. 46).

HIV testing is rarely a one-off event, and the expectation of regular testing is also associated with increased anxiety. Jon reflected on his experience of being reminded that he was due to be tested: "… let's say, I'd get a notification; it's like, 'Oh, it's been three months since you've been, are you gonna go in for another test?' and that's probably when the anxiety would come. So, I think it was always more around testing, really" (Para. 36). Anxiety induced by the frequency of HIV testing can result in avoiding being tested. Daniel explained the reasons why he did not engage in testing as much as he would have liked: "Not as frequently as I'd like, and there would always be … so, I would be waiting to get the test and it would always be worst-case scenario in my head" (Para. 50).

Waiting for the result of an HIV test is associated with acute anxiety that impedes ability to engage with other demands, such as employment and self-care. Nathan explained that "for me, how they were? Oh, <sighs> I would get very little done, thinking about this and that … and keep thinking about it constantly, so not a really pleasant experience overall" (Para. 16).

You've reset. Although the experience of having an HIV test is aversive, in anxiety both before having the test and when waiting for the result, the experience of receiving a negative result provides psychological relief. For instance, Paulo said of receiving a negative result: "when you had the results that is negative, is like you feel that's a huge weight is lift from your back." (Para. 55)

The potency of a negative result has the potential to temporarily eliminate anxiety through certainty of being HIV negative: "… because I always felt like, once you go into the clinic and the clinic was like, 'You're fine!', it kind of felt like you've reset or something, like you're, 'I'm totally fresh', something like that" (Marcus, para. 51).

Given the psychological relief that is associated with receiving a negative HIV result, this can be used as a strategy to elevate HIV anxiety. Hamish said this of his pattern of testing: "I have used it to relieve anxiety, but it is painful to get to that stage; because of the three-month window, it could be a long, painful wait." (Para. 72)

Domain Four: Motivation for, and initiation of, PrEP

Five themes and ten subthemes were constructed summarising participants' motivations for, and the experiences of initiating, PrEP.

Theme one: How did I manage it? I just didn't!

The persistence and intensity of HIV anxiety can overwhelm and be experienced as unmanageable and intolerable, which serves as motivation for initiating PrEP. Finn said this of his of his HIV anxiety: "How did I manage it? I just didn't! I just … I ended up just probably drinking too much as well …" (Para. 74). Presenting to sexual health clinics in an anxious state can lead to clinicians to tentively recommending PrEP to reduce psychological distress, especially in the context when participants repeadedly attended.

I wasn't trusting condoms. It is acknowledged that condoms significantly reduce HIV risk, but they are conceptualised as problematic. Marcus said that "I recognise condoms are pretty fail-safe; except sometimes" (Para. 76). A sense of a lack of control regarding whether a condom fails may result in a lack of trust. For example, Paulo explained "Yes,

because I never trust 100% in a condom, because … things happen … and I could be infected. It's not 100% reliable and it's just a barrier …"

In the context of a condom failure, this can be internalised as a personal failing and lead to negative cognitions regarding responsibility.

When condoms fail it can be challenging to reassure the other partner, which can lead to feelings of guilt when unable to negotiate the conversation. Daniel reflected: **"**…the condom broke, and the other person said, 'Oh, no, I'm fine, I'm a nurse,' and all this stuff, 'Are you OK?' and I was like, 'Oh, yeah, yeah!' But I didn't really know … that was a wrong thing of me." (Para. 20)

Initiating PrEP is a means to mitigate against the lack of reliability of condoms. Marcus remarked: "Condoms have their breaks, but this is like the insurance policy, that's the way I kinda look at it" (Para. 8). This lack of trust in condoms can also lead to ambivalence and resentment. Mateo stated that "I was starting to get a bit of condom-fatigue" (Para. 16).

I need to enjoy myself before it's too late. Participants expressed a sense of urgency to engage in sexual behaviour that is absent of anxiety. There appeared to be a sense of sadness and loss, in relation to their sexuality, as a consequence of HIV anxiety. PrEP was perceived as a route out of this and gave a sense of hope. HIV anxiety is associated with sexual inhibition which can lead to a resentment and frustration. This is perpetuated by a perception that they would no longer be sexually attractive and be able to engage in sexual activity. Yusuf said: "I want to experience more because if I'm not going to experience a lot soon, then I won't experience as much as I want" (Para. 110).

Because of HIV anxiety, sex is not as enjoyable and therefore PrEP offers a way to reconnect to their sexuality by muting anxiety. For example, Marcus said that:

> "I'd say, 'Oh, it's OK, I don't think I've ever enjoyed sex anyway.' Like, I'd said something flippantly like that in different ways and they took it as like, 'Have you –' Well, actually that's what led to this conversation, that's how this whole thing

> happened, that I was referred to [the clinic], because I got referred to, or it was suggested, 'D'you wanna speak to a counsellor?'" (Para. 35)

Perceived ageism in the gay community, especially in the context of those in sexually submissive roles, can increase the sense of urgency to engage in sexual behaviour and therefore increase motivation to initiate PrEP. Yusuf explained:

> "…because I feel like there was this party going on, and I arrived at the party, it was about five minutes before the closing, so I need to … I feel like I need to make the best of it, because the entire gay and kink community is telling me that in two years I need to forget about sex and being a sub" (Para. 109)

Regret over abstaining or inhibiting sexual activity can result in people feeling like they have missed out, in comparison to their peers. For instance, Daniel said this of his motivation to start PrEP: "I probably didn't have as much fun as I should have done, when I was a lot younger. And in some ways … I regret that I didn't have what a lot of other people had …" (Para. 15)

Theme two: Responsibility

Initiating PrEP is viewed as being responsible and a way to proactively reduce subjective HIV risk. For instance, Marcus reflected: "But it's just like, what a great insurance policy PrEP is. And I use that phrase, because it's happening in the back … sorry, it's taking care or something without you having to do anything and …" (Para. 63)

It's irresponsible of me to go and do that. There is a tension between the view that anal sex without a condom is irresponsible and yet this being the sex that is sought by some. Initiating PrEP results in condomless anal sex being viewed as more responsible, and therefore more favourable. Nathan explained: "I accept that if I want to play that way, there are possibilities that can happen and that it's my duty to myself but also to others, to be as straightforward as possible and to test regularly" (Para.77).

Condomless anal sex within relationships is something that can be missed when the relationship ends. In this instance, PrEP can offer an opportunity to facilitate anal sex without compromising a self-view of being responsible. Dirk said this of his desire to start using PrEP: "But then after that, that relationship ended and I was like, 'OK, I do still really like unprotected sex, <laughs> but it's irresponsible of me to go and do that with just anyone I meet online, or anyone I meet in general'" (Para. 24).

The sense of responsibility is not confined just to their own health but also to that of their partners. Taking PrEP is a means to protect other people; for instance, Dirk said "this is the responsible thing to do, because I don't wanna unknowingly have something and then give it other people'" (Para. 47). Daniel likened his motivation for taking PrEP to health behaviours associated with COVID-19:

> "… everyone has a responsibility to wear a mask in a shop, and to socially distance where they can. And to me that's equally the same, it's another virus that instead of you transmitting through coughing, you transmit it through blood and semen and stuff. And why wouldn't you want to safeguard other people?" (Para. 87)

Anxiety associated with the possibility of infecting others with HIV can result in a reluctance to engage in sexual behaviours. Initiating PrEP can be motivated by a desire to reduce this anxiety due to the perceived increased protection it affords the user (and by proxy, their partners). For instance, Dirk explained: "Not very frequent; because of the whole situation, I just felt a lot less … eager to have sex. No, that's not true! <Laughs> I think I just generally felt like I could have been putting people at risk, which … so I don't know why I thought that." (Para, 105).

I've always been the serious one. Being responsible in relation to the preservation of our own health is viewed as a pro-social behaviour and therefore valued. Dirk said this of his decision to initiate PrEP:

> "And I also wanna protect myself, so I started looking into it more; there's a few people I follow online who are also like advocates for PrEP, as well. It became more relevant for me, specifically, and so I wanted to make sure that I was protecting

> myself and the people I was possibly having unprotected sex with, or any form of sex with." (Para. 24)

Pursuing behaviours that are seen as responsible (i.e., taking PrEP) can be a consequence of the roles we have in our lives and the expectations associated with these. Daniel said: "I've always been the serious one in the family, so there's always been an expectation that I would be the responsible, or that's the burden that I've always felt from them …" (Para. 12). Paulo explained that he felt as a nurse it was his responsibility to take PrEP after a condom failure: "Oh, my God! How can I, as a nurse and believing that the condom is a good thing and protect effectively, how can I be failing so basic act that just protect myself and other person?" (Para. 12).

The motivation for initiating PrEP can also be associated with a view that it is responsible to reduce anxiety-associated behaviours, such as seeking repeated testing. Daniel explained:

> "And I think everyone should be able to be in charge of their own bodies… you get some people that are so worried about themselves that they go and get a medical every six weeks sort of stuff and pay fortunes for private check-ups and scans and ancestry and blood tests and DNA and all the other stuff, because they're worried about … I'm not to that level, but it's sort of like … my mindset is, 'Well, why wouldn't you want to protect yourself?'" (Para. 52)

Theme three: Accessibility

Socioeconomic factors, such as income and employment status, can impact on an individual's ability to access PrEP. Mateo reflected on his inability to purchase PrEP: "…at first, I was a student and then I was unemployed for a few months and then I was on minimum … well, not minimum wage; I was on a very low wage. So, I couldn't really afford it …" (Para. 16)

The IMPACT trial can be viewed as an attempt to placate those pushing for increased access, whilst continuing to not offer universal access to those who would benefit. Mateo said of the trial: "… I know there wasn't really a trial, it was a manoeuvre by the NHS to pay less for it and delay the roll-out." (Para. 103). The view that PrEP should only be accessible to those who are high risk is contested and undermines personal choice. Daniel explained that he would continue to access PrEP privately if he was unable to access it via NHS:

> "I think it's important that everyone has a choice; everyone has autonomy over themselves, and I think everyone should be able to do what they need to do. If it wasn't on the NHS in the future, I would still pay for it privately, that's my position because it's providing me with a level of reassurance." (Para. 52)

It's just another forestall. The impressive outcomes reported in the clinical trials can be difficult for some to believe. Hamish recalled his initial impression of PrEP as a strategy to reduce HIV infection: "It seemed a bit too good to be true, and I was like, 'Well, yes, maybe it's an improvement, but unless it's pretty near 100%, then it's just another forestall', I suppose" (Para. 28). Anecdotal reports that PrEP is close to 100% are not viewed as supported by clinical trial data; its efficacy was therefore initially met with caution. For example, Yusuf said:

> "I would love to say … it is actually 100%, but the cases where the people actually quoted was, they didn't take it properly and stuff. But I don't know if that is saying, not taking properly, it doesn't sound very scientific to me." (Para. 54)

Phoney medication. PrEP that is self-sourced and a generic formulation of the drug can result in anxiety over the authenticity (and thus efficacy) of the treatment. Nathan said "well, it made me think that if I get it from an official source and I know that at least I'm not getting phoney medication. Which is a bit of a terrifying thought, but for something like that I will never consider that" (Para. 44).

Engaging in pharmacokinetic testing to determine the effectiveness of the medication via NHS clinics provides some, albeit fleeting, reassurance for those who are sourcing generic formulations of PrEP. For instance, Mateo said this of accessing generic PrEP: "[the

clinic] were sort of saying, 'We can't give you the PrEP itself, but we can test you to see if you have the right levels of it'. I was sort of on and off because I didn't trust it that well; it was fairly new, I could never be certain …" (Para. 16).

Theme four: Daily is best for me.

There are various factors that motivate one to take PrEP daily. For instance, Finn explained:

> "I'm trying to get back into daily because occurrence is probably not … it's kind of hard to plan when you're gonna have certain experiences <laughs> like that, so … even though I would persist in using condoms during sex, it's still … I still like to know that I've taken it…" (Para. 41)\

Things are not always planned. Using PrEP daily is associated with the ability to engage in sexual behaviour spontaneously and without the need to forward plan. Dirk explained that "… and I don't like the idea of having to plan out sex, if that is gonna happen, like that you have to take one dose 24 hours before and then two doses afterwards or something" (Para. 37). In the era of geospatial applications to facilitate meeting others for sex, planning for sex is not always practical. Yusuf said "… and these things are not, especially in the era of Grindr, these things are not always planned. It's very spontaneous and everything" (Para. 33).

Daily PrEP may result in a decrease in HIV risk and therefore afford opportunities to engage in spontaneous sex. Jon said this of his choice to take PrEP daily: "Yeah, because I kind of think, if the mood does strike me and I suddenly think no, get over yourself, if I start to feel a bit better, I wanna just be able to … just get on with it, <laugh> and not have that worry" (Para. 81)

Uncertainty regarding the effectiveness of event-based dosing and one's ability to manage the regime can undermine confidence. Conversely, taking PrEP daily reduces uncertainty, increases confidence and, ultimately, trust in its effectiveness. Dirk explained:

> "I think the reason I don't just wanna use it when I am about to have sex, is just because I feel like, 'What if I didn't take it long enough in advance? Or, too long in advance? The 24 hours; what if it was 19 hours? Or what if it was too long ago?' I don't know the science well enough to trust that aspect of it, or myself, so it just seems to … makes more sense to me." (Para. 43)

I know that … there is sex going on. In the context of an open relationship, daily PrEP offers an increased sense of safety to both the user and their partner. Daniel reflected on his decision to take PrEP after opening his relationship with a partner:

> "[He is] going to a number of different parties with lots of friends that he's recently met and it's sort of made me a bit nervous, because I know that … there is sex going on and stuff, so I just want to make sure that … I don't know whether it's always protected sex, so I always wanted to safeguard myself as much as possible." (Para. 26)

I'm very good at maintaining a routine. The taking of PrEP daily allows for it to be incorporated into one's routine. Daniel explained that "…and for me, a routine … I'm very good at maintaining a routine, it's sort of like … it removes that what-if situation in my head again" (Para. 24). In turn, this is perceived to make it less likely to be taken incorrectly (therefore maximising protection). For instance, Paulo said: "I felt I could be more protect, because taking every single day, even though they say it's OK taking one situation. I think for me to be organised and to avoid forgetting to take the PrEP, I built up, wrote in every single day to take the tablet in the morning." (Para. 22)

Theme five: EBD works best for me

Although most participants reported taking daily PrEP, some did use event-based dosing (EBD). Taking medication daily in the absence of sexual contact can be viewed as unnecessary. Hamish, for instance, explained: "Mostly on-demand, so like, you know for the

weekends when something … sometimes for longer periods … Well, because I wasn't having sex all the time, and it didn't seem necessary to take medication all the time when it wasn't necessary." (Para. 32-34)

Domain Five: The experience and impact of PrEP

Five themes and seventeen composite subthemes were constructed summarising participants' experience and the impact of using PrEP.

Theme one: Facilitating a sexual life

Taking PrEP impacts positively on sexual functioning and satisfaction and therefore facilitates a sexual life that is congruent with one's sexuality. For instance, Yusuf said:

> "I'm actually taking all precautions that science allows me to take, so… I wanna have sex. <Laughs> I wanna have a sexual life. And I'm incredibly sexual…I've always been incredibly sexual. And a bit kinky <laughs> as well. So, I was like yeah, I wanna live my life and taking PrEP … was one of the best things that happened to me." (Para. 24)

Express myself sexually. Using PrEP can facilitate engagement in sexual behaviours that were previously avoided due to HIV anxiety. Marcus said this of the changes in his sexual behaviour:

> "I'm 44, I almost never performed oral sex, and not because I didn't want to, but because I just saw it as like super-high risk, even though I knew the … people like you with … clinicians would say, 'No, that's not exactly the case,' and all that. So, I could never … and since PrEP, although again I just think in general, it's just quite personal, so I don't really like to do … unless I really like the guy I don't do that kind of thing, but I have engaged in it, which is like, and it's been enjoyable, just because of PrEP. That is 100% PrEP." (Para. 99)

More generally, PrEP can be attributed to sexual expression that is congruent with ones

sexual desires. Hamish reflected on the role of PrEP in sexual expression: "I always had a bit of a terror of HIV, back in the eighties, nineties. And somehow I seem to have got to a stage in my life that I've moved on from that and this gave me an opportunity to express myself sexually in a way that I hadn't really tried to do before" (Para. 14).

It's just pleasure. Before taking PrEP, sex was often associated with significant stress and anxiety, which impacts sexual satisfaction. After taking PrEP, the reduction or removal of HIV anxiety facilitates increased sexual satisfaction. Yusuf had this reflection: "The fear bit is completely, it's been stripped away and … now it is what it's supposed to be. It's just pleasure … well, and pain if you want to!" (Para. 98).

The negative consequences associated with sexual contact are weakened and this results in greater sexual satisfaction. Finn explained: "And now I'm a lot more … though I have, as I said, a bit of anxiety, it's not massive, and I think it's not massive, but I definitely don't link catastrophe to sex anymore <laughs> which is the main thing. And it allows me to enjoy sex" (Para. 84).

Increased sexual satisfaction is also a by-product of feeling more protected against HIV and the associated positive affect and confidence. For example, Paulo said:

> "I can tell you, I feel more relaxed and more confident at the same time, even though I have this perception that risk might be high, I think I'm more protected. So, it's 90% more of protection that I hadn't before, so that gives me more confidence and I can enjoy more sex without concerns. Or, not much concerns." (Para, 87)

The reduction in the cognitive load associated with HIV anxiety, allows for attention to be focussed on arousal and sexual enjoyment. Nathan, for instance, noted:

> "Well, I guess that being able not to worry specifically about that, means that your mind, or in this case my mind, can be fully focused on the actual enjoyment. Of course, I'm sure that you will know that, I mean being a man yourself, that when we are in the heat of the moment, we really don't think that much. Because like someone I knew once said, 'The Lord gave us both brain and genitals, but only enough blood to get one of them working at a time!'" (Para. 177)

I enjoy bottoming. PrEP use is associated with changes in sexual positioning. Specifically, receptive anal sex is an activity that one engages more frequently. For instance, Hamish said "… it's made me better able to express what I want to be, as a gay man, yes" (Para. 166). Satisfaction during receptive anal is also increased; for example, Nathan said: "… because even now, I'm still very surprised at how much I enjoy bottoming" (Para. 198).

In the context of latex allergy, receptive anal sex is more enjoyable as it allows for condoms not to be used. For instance, Nathan reflected:

> "… because of the allergy, yes. And when I go without it, these problems have been minimised. Of course, one could argue that the risk of becoming HIV- positive outstrips the risk of suffering a little bit from piles or whatever they're called, haemorrhoids, or things like that, which is where PrEP comes into account." (Para. 161)

More prone to doing it. A reduction in anxiety and increase in sexual satisfaction results in engaging in sex more frequently and with more partners. Nathan said: "But being able to it do it with greater serenity and without all the collateral issues that I mentioned before, have definitely made me a little bit more prone to doing it" (Para. 196). PrEP recalibrates risk tolerance through less thorough and sensitive risk assessments. Marcus, for example, said: "… actual sexual activity I would say, increased, because I have less … fear around it, so there's less of a decision tree in my head, like, 'Is it really worth it?', like, I'd kind of say, 'Is it really worth hooking up with this guy'" (Para. 98).

In the context of sex within a relationship, an increase in sexual activity is associated with the reassurance PrEP gives in protecting against the acquisition of infection from their partner. For instance, Daniel stated:

> "It happens more often, because every time that we used to do it, I would be thinking, 'Oh, he was at a party the other night; Oh, what if this happened?' Again, worst-case scenario, so sometimes it'd be like, 'Oh, I'm not in the mood, he's probably had his fill,' sort of stuff." (Para. 61)

Theme two: Change in risk perception

Activities that were once considered to be high risk are downgraded after using PrEP.

I'm much freer now. The protection afforded by PrEP results in engaging in sexual practices that were previously deemed too high risk. For example, Mateo said: "So yeah, to answer your question, I think it can be for a lot of people, because in a way it's a sort of get-out-of-jail-free card, if that makes sense? So, a lot of people wouldn't have put themselves … wouldn't have joined certain scenes if it weren't for this, I suppose." (Para. 139). There is a sense of being liberated from risk; for example, Hamish said: "Now, I'm much freer now. Now I will have anal without condoms, fisting … no, I feel much more liberated in what I can do." (Para. 110).

Although some may not seek out 'riskier' situations, their tolerance of risk is higher. Finn, for example said this:

> <Pause> I mean in a really honest way, I suppose … if an incident happened that I … I suppose I'd be a lot more comfortable with letting someone … letting my body touch someone's body without a condom. Not necessarily inserting but like just really edging and stuff like that, that I wouldn't have done before. And I wouldn't be so fearful about it anymore. (Para., 88)

As the threshold for risk increases, this is not always welcomed and can lead to regret and shame. Yusuf, for instance, spoke of using drugs during sex for the first time:

> "I once … there was this cute guy who invited me to a chill-out. I didn't even know what a chill-out meant. I asked him to explain to me what it is and I went there. Oh my god! They were … pumping stuff up their holes. I don't know what it was. And I was like, I tried G there for the first time in my life and I don't think I want to try it again." (Yusuf: 134)

Theme three: Disclosing I'm on PrEP

Telling others about taking PrEP can be challenging at times, given the expectations.

Oh, you're on PrEP and you're also using condoms? It is perceived to be uncommon to use PrEP and condoms simultaneously and therefore potential sexual partner(s) are perceived to sometimes make negative judgements. For instance, Yusuf said: "But of course one of the things that people are always very surprised that, 'Oh, you're on PrEP and you're also using condoms?' That is … stupid to many people. They can't understand." (Para. 103).

Geospatial applications used by gay and bisexual men have the option for users to display whether they use PrEP or not. Dirk said this of people contacting him on an app: "I have put it on dating app profiles … Oh God! … it's on my Grindr. I don't know if that makes people assume that I really want to just have bareback sex with them. I've had people reach out to me specifically because of that." (Para. 149-150)

I have to justify it. The association between PrEP and high-risk sexual behaviour leads to some having to justify their motivation for using PrEP to mitigate any negative judgements that may be made by others. Finn, for example, said:

> "I always had … it's weird, I always have to justify, if I talk to my friends about it, 'cause they ask about it or have a conversation and I kind of explain what it is and then I always have to explain that it's not because I'm having loads of sex; it's just because … I have to justify it, in a way, which … is absolutely ridiculous when you think about it. But –" (Para. 177)

It's good for people who have anxiety. There is a motivation to promote the positive experience of using PrEP, in the context of HIV anxiety. Daniel said this:

> "because I wanted to demonstrate that it's good for people that have anxiety to be able to access it, 'cause it means that they will go and test, they'll go to the clinic, they'll be more … they'll have more open, frank conversations, they'll have a more active and enjoyable life and … I know I have stopped doing stuff in the past, because I just psyched myself out too much, thinking, 'Oh, worst-case scenario.'" (Para. 87)

Theme four: STIs

Other sexually transmitted infections (STIs) generate less distress than HIV.

It's more of a chore. Testing positive for, or being informed you are a contact of a person with, an STI is perceived as inconvenient due to having to physically attend a clinic. For instance, Nathan said:

> "It's more of a chore to actually go there and get the injection and being really assertive to health operators on the phone; because apparently, the health policies of sexual health clinics keep changing about whether to give the preventive shot or not, or to simply not, or keep monitoring. I was more bothered about actually having to go there, rather than from the actual thing itself." (Para. 87)

It's like 'och!' Although testing positive for an STI is stigmatised, this appears to be less impactful than stigma associated with HIV. This may be a result of the transient nature of STIs. Finn reflected on his experience of being diagnosed with STIs since using PrEP:

> "With gonorrhoea and chlamydia, it's like 'och!, what's the clinic gonna think?' I'm kind of rationalising it, I'm not gonna see those people again, they're there for a reason, there's no judgement there, I don't need to tell my friends and family, they don't to know about it, we can treat it. I can kind of package it differently, whereas with HIV it's a lot more 'cause I'm like I've gotta take pills for the rest of my life, my parents are gonna disown me, they're gonna know because I'll have pills with me all the time, all this stuff goes on in my head and it's just like it's absolutely tiring for my mind to think like that, and I don't know why I think like that." (Para. 170)

It's a short-term issue. The impact of STIs on one's health is perceived to be less severe and therefore they are associated with less distress. Marcus explained that "I guess realistically, if you were to get something else, or a lot of things you can get, you could take an injection for, pill for, whatever; it's a short-term issue … HIV is just like capital letters in red, you know, very bright kind of thing, whereas the others are just like a whole suite of crap. But this is just different, so that dropping off has completely reduced my anxiety, yeah" (Para. 91).

The imagined guilt one would experience if they passed on an STI to their sexual partner(s), compared to HIV, is less. Consequently, the distress associated with the potential of an STI is less. For instance, Dirk reflected:

> "I know that they're treatable, most strands; there is some untreatable ones, but I'm pretty sure they're very rare. So, I know that they're treatable, and so I think it's a case of there's less worry about … it feels less serious… this is the wrong phrasing, but it feels less serious to give someone gonorrhoea or chlamydia, than it is to give them HIV, because HIV will define the rest of their life, whereas gonorrhoea defines the rest of their next three weeks while they take antibiotics, or however long depending on the infection. But yeah, it feels less serious; obviously it's still not ideal and you should be responsible with your sexual health and the sexual health of others, but I think it feels, for me it feels less of a horrible thing to do to someone, even if you are doing it without knowing." (Para.130)

Theme Five: HIV Anxiety

Taking PrEP results in a reduction in HIV anxiety. Nathan stated "Well, by taking it, it means that I no longer have to worry constantly about becoming positive" (Para. 104). The association between being gay and HIV is weakened. For instance, Mateo said "because I think a lot of people had a lot of HIV anxiety and trust issues, which are now irrelevant. So, please feel that they're in control again and that that … the link between gay sex and disease and social stigma is no longer relevant" (Para. 105).

The reduction, or in some instances, the removal of HIV anxiety can lead to less stress in one's life and thus promote psychological wellbeing. Jon explained:

> "I see it as a way of just taking a little bit of worry out of my life, knowing that if I have sex and anything were to go wrong, I've just got that extra bit of protection … in the same way that contracepti– you know, that condoms do that, or the same way that getting a vaccina– getting the hepatitis B vaccination or getting the HPV vaccination gives that … it just gives me a little bit less worry in my life. And I kinda think, 'I've got enough worry in my life as it is, so why not take something that's just gonna make it even easier?'" (Para, 68)

PrEP is a relatively easy way to control anxiety that does not require a lot of effort. For example, Marcus said:

> "… it's sounds a bit weird to say this, but you know with this COVID thing? You'd think, 'Oh, sure you just have to wipe your hands,' or you think, 'Oh, but maybe you did use your phone when you were coming back from Waitrose, and then you did reach into your pocket when you were coming to get your keys, so now, even if you wash your ha –' you know, it's that thing where you're like, it's too … it's not something we can control … whereas PrEP, <clicks fingers> it just took care of all that." (Para 43-17)

Let my guard down. The reduction in anxiety associated with sex is often gradual and incremental. Consequently, changes in sexual behaviour are often not instantaneous. Marcus, for example, said this:

> "…I was fully conscious of where everything was, but that's exactly correct, yes. And I notice the difference, but what's interesting is, I didn't notice the difference for example in performing oral sex, I didn't really clock it 'til I think it took me a year of being on and off PrEP… before I let my guard down." (Para. 101)

I still have those anxieties. HIV anxiety can remain, especially post sexual activity. However, the intensity is less. Specifically, Finn said this: "But now I'm a lot more comfortable being … I feel more comfortable being myself and … although I still have those anxieties and sensations afterwards, it's a lot more minimal than where it was." (Para. 76). Despite the impressive protection offered by PrEP, some continue to worry about being the exception. Paulo, for example, said: "<Pause> It's … <sigh> because what say the evidence when I start to read that was like 90% is … 95 or 90 or almost 99% effective and the question is … 'What if I am the 1% that is not effective.'" (Para. 73)

There is HIV in my life. Because of using PrEP, avoidance of people who are living with HIV to mitigate anxiety is reduced which has made exposure to previously feared stimulus more tolerable. For instance, Mateo said "So, I think going on PrEP not only made those things irrelevant, but it also allowed me to expose myself to what was a really irrational, paralysing fear. And thanks to that exposure, kind of overcome it" (Para. 109). In turn, this allows for social and sexual connections to develop with PLWH. Mateo said this of his new friendship:

> "I think about it, but in an unemotional way … if that makes sense? For example, my … this person that I mentioned that I met, who was living with HIV, has now become my best friend, because we have lots of things in common, not for any other reason. So, <sighs> there is HIV in my life and I also know that his experience of dating, for example, is very different to mine …" (Para. 93)

The next one in the line-up. Despite a reduction in HIV anxiety, some develop new targets for anxiety. Dirk said: Yeah, it's been less so recently, thankfully, because I've been on many other things that are also a little bit scary, such as coronavirus" (Para. 81). These targets are often other STIs. For example, Marcus made this observation:

> "because I had this HIV fear factor… I quite accept that if I take PrEP and I use a condom… I should be OK <laughs>. Mostly what I think of the condom would be feel uncomfortable, but maybe PrEP I feel somehow, I've got some invisible protection, right? But I realised that once that left the equation, the next most … the next one after that, the next STI or the next one in the line-up of fear factors, took its place. Which is interesting, I didn't quite expect that. Less so; of course, it's not HIV." (Para. 30)

Despite anxiety persisting – albeit regarding another target – the intensity is less. Marcus said: "… yeah, that is interesting, isn't? That was a bit of a downer, when I realised that, to be honest. Although logically there's no change, it's just a better situation than before, but I did … yes it's a bit of a downer." (Para. 78-80)

It's going to be taken away from me. There is anxiety around the possibility that the positive impact of taking PrEP on one's psychological wellbeing may be transient. Yusuf shared this: "But right now, also because I'd just started living an actual sexual life that I wanted to live, and it's going to be taken away from me is how I'm feeling. That is the constant reason for anxiety for me right now. That is why I can't really say my mental health is well" (Para. 160).

Bouts of anxiety that I can kind of manage. PrEP is viewed as a tool that assists those with HIV to overcome their anxiety and live their lives more fully. Jon said this of his experience of anxiety: "… it is tiring, but I think there's an element of although the

opportunity doesn't present itself as much anymore, I think I've gotten better at managing it" (Para. 61).

PrEP is seen as a more attractive intervention for HIV anxiety than anxiolytic or antidepressant medications, due to the lack of side-effects. For example, Finn said this:

"'cause I think for me, a lot of anxiety came around this and for me it's easier for me to take PrEP with no psychological effects, rather than me self-medicate on anti- anxiety medication or the antidepressants or anything like that. Because it doesn't have any psychological effects, but it keeps my mind level and then when I do have bouts of anxiety I can kind of manage those." (Para. 18)

CHAPTER FOUR: DISCUSSION

Chapter Overview

In this final chapter, there will be a summary of the findings in relation to psychological theory and previous research. There will also be a critical appraisal of the current study, highlighting key limitations and strengths. A discussion on the clinical implications of this thesis will be presented, along with recommendations for future research. Finally, I will conclude this chapter and thesis with a reflexive statement where I will re-consider my own position in this research.

Summary of Findings

Twenty-two themes and forty-nine accompanying subthemes were extracted from participants' data, reflecting the five key research aims. Findings for each of the research aims are presented and discussed below, with reference to psychological theory (particularly cognitive-behaviour theories and models) and previous research.

How does HIV anxiety develop and manifest in these GBM?

Development of HIV anxiety. Participants discussed growing up in heteronormative societies and frequently felt pressure to reject their homosexuality and try and adopt heterosexual relationships. For some participants, this experience of heteronormativity was perpetuated by prevailing cultural and religious expectations in their families and communities. In some cases, it seemed that the privileging of heterosexuality led to internalised homophobia. More specifically, some participants experienced negative reactions when disclosing their sexual identity to their family and friends. This finding is in keeping with previous research from a developmental perspective that highlights the role of early parental disapproval and

gender nonconforming behaviour (i.e., homosexuality) in GBM developing anxiety disorders in adulthood (Landolt et al., 2004; Skidmore et al., 2007).

As previously mentioned in the introduction chapter, Meyer's Minority Stress Theory (2003) suggests that societal stigma compromises GBM's mental health through several psychosocial stress processes, which are unique to this group. Several of these proposed processes were evident in the experiences of participants. Firstly, Pachnakis et al. (2008) proposed that stigma-based rejection sensitivity may predispose GBM to developing anxiety disorders. Several participants described that they had learnt to anxiously anticipate rejection because of previous experiences with prejudice and discrimination towards homosexuality. This experience appeared to be more acute in the context of participants who had conflicting group memberships, such as instances where homosexuality was incompatible or pathologised in their religion or cultural identity. Secondly, Pachnakis (2007) also suggested the process of concealing one's sexual identity can lead to psychological distress. Participants discussed their experiences of supressing their homosexual identities, either through splitting (i.e., not integrating their authentic sexuality into other areas of their life) or rejection (i.e., pursuing heterosexual relationships and resisting pursuing activities associated with homosexuality). Some participants even discussed being hypervigilant of their own 'sex-atypical' behaviours (Sylva et al., 2009) and actively trying to moderate these behaviours to maximise concealment of their authentic sexual identity; in doing so, they protected themselves against being exposed and therefore also from the possible harassment and discrimination they may have experienced.

As mentioned above, internalised homophobia is thought to be particularly potent in the development of anxiety disorders in GBM (Meyer, 1995, 2003). In relation to HIV anxiety, internalised homophobia appears to be particularly relevant. Specifically, in the context of prevailing narratives of HIV being a 'gay disease' and commonly associated with promiscuous behaviour, which is viewed as synonymous with the gay identity (Jaspal and Bayley, 2020),

participants discussed the fusing of HIV and homosexuality. These terms were intrinsically related; being homosexual meant that you were going to acquire HIV, or you were already infected. These beliefs regarding HIV and homosexuality become more alarming as the participants sexual identity became more apparent to them. In turn, this appears to trigger psychological distress in the form of anxiety about acquiring HIV.

It is thought that whilst the impact of internalised homophobia is most acute in the initial stages of recognising one's authentic sexual identity (Cass 1984; Troiden, 1989), it is something that persists throughout the life course of many GBM and directly impacts on psychological wellbeing (Hetrick and Martin, 1984; Stein and Cohen, 1984). In the current study participants discussed their own experiences with internalised homophobia, especially in relation to HIV; in turn, there appears to be a relationship between internalised homophobia and HIV-specific stigma, and the development of HIV anxiety. However, it should be noted that whilst internalised homophobia narratives that include HIV-specific stigma appears to be a common phenomenon among GBM (Berg and Ross, 2014; Smit, 2012), not all GBM go on to experience HIV anxiety (Odets, 1995; Scragg, 1995).

It is conceivable that because of internalised homophobia and pervasive HIV-specific stigma, participants may have developed negative attitudes towards sex, which inform their subsequent sexual behaviours, and which in turn are conducive to HIV anxiety. Specifically, participants often had sex-negative attitudes towards sexual expression of GBM and themselves, such as sex, especially causal sex, being associated with danger. Furthermore, the two-factor learning model theory model of phobias (Mowrer, 1960) posits that anxiety is generated through classical conditioning – pairing of a stimulus with a perceived aversive experience, which results in anxiety. This is then maintained by operant conditioning – an avoidance of the stimuli in the short-term leads to a reduction in anxiety (and it is therefore cyclical). Participants discussed their relationship to sex (prior to starting PrEP) being

associated with anxiety and catastrophic predictions (i.e., acquisition of HIV infection and the perceived consequences) and, for some, this led to avoidance of sexual activity. According the two-factor learning model of phobias (Mowrer, 1960), this avoidance prevents the individual learning that the predicted adverse outcome will not be realised and/or their ability to cope is superior to their initial prediction. As such, this avoidance may have strengthened anxiety around sex and resulted in cognitive patterns (i.e., hypervigilance and selective attention) that serve to perpetuate and maintain HIV anxiety.

Another important theoretical concept to consider in the development of HIV anxiety in these participants is 'vicarious learning' and 'negative information' (Rachman, 1977); these may serve as a pathway to HIV anxiety. Specifically, some participants reported direct exposure to HIV, through caring roles for example, which was particularly pertinent for those who had been sexually active in the 'pre-HAART' era, where the consequences of HIV were drastically (and objectively) different. While other participants had very limited direct experience of HIV, insofar as they had not witnessed illness or loss because of HIV, most participants did tell of their experience of homophobia and the pervasiveness of HIV-related stigma, which may be considered 'vicarious learning' and/or 'negative information'. Furthermore, some participants had negative sexual experiences where a partner (often in the context of casual sex) attempted to remove the condom or, according to the participants, was the source of an STI. Non-consensual removal of condoms, colloquially referred to as 'stealthing' (Brodsky, 2017), is a common practice. A cross-sectional survey conducted in a sexual health clinic in Melbourne, Australia, found that a fifth of GBM involved in the study reported being the victim of stealthing on a least one occasion (Latimer et al., 2018). Despite this, it is unclear as to whether this precipitated HIV anxiety or occurred within the context of HIV anxiety (e.g., through selective attention and/or hypervigilance).

Experience of HIV anxiety prior to PrEP. Participants told of their experience of HIV anxiety which involved a variety of cognitive patterns and behavioural responses. Participants concluded that HIV anxiety was part of them and conveyed a chronicity to its duration. Specifically, some participants thought that it may be a component of a mental health diagnosis, such as obsessive-compulsive disorder, and others thought that personality traits were conducive to HIV anxiety (i.e., being naturally pessimistic). HIV appeared to have a special status that could induce intense fear.

HIV anxiety was omnipresent (although at varying degrees) for participants. It was considered a reality for GBM, in the idea that becoming infected was inevitable, due to their identity as a GBM. Participants appeared to overestimate their risk of HIV and, to a greater extent, the risk other GBM posed to them. This may be considered an example of 'overestimation of threat', which is defined as "an exaggerated estimation of the probability or severity of harm" (Morrison and Westbrook, 2004, p102-103). This is a common feature in those presenting with anxiety disorders, especially in OCD.

The experience of being vigilant to the presence of physical symptoms of HIV was a common experience among participants. Some participants also recalled their experience of scanning their bodies to reveal potential entry routes. Furthermore, it was also common for benign body changes or sensations to be interpreted as dangerous and ultimately a sign of being infected. These experiences are captured within the cognitive behavioural model of health anxiety (Warwick and Salkovskis, 1990) and OCD (Salkovskis et al., 1998). Within the health anxiety model, it is suggested that the arousal process, which is triggered by anxiety, generates bodily changes which are in turn misinterpreted as illness (i.e., HIV). Although participants did experience physical manifestations of anxiety, they also experienced unrelated symptoms which were misinterpreted as HIV; this was often in the context of repetitive body checking.

Furthermore, participants often experienced intrusions and urges to check their bodies before, during and/or post sexual contact. This experience is therefore most adequately captured in the OCD model, in which this checking behaviour may be considered a neutralising action (e.g., ritualistic behaviour that extinguishes the anxiety).

As previously discussed in the introduction chapter of this thesis, the role of shame has been highlighted as a main challenge to cognitive-behavioural models used by some to conceptualise HIV anxiety. Some participants' fear of HIV was around the possibility of illness and death; however, for some, it was the stigma and shame that is associated with HIV and not a fear of any physical manifestation of the virus. Specifically, participants were particularly fearful of the perceived negative judgement and rejection they may face if HIV-positive. This is considered external shame (Gilbert, 2010a), and therefore highlights the importance of including theoretical models of shame into our understanding of HIV anxiety, which is largely absent in cognitive-behavioural models.

Participants engaged in a variety of behaviours aimed to preserve their HIV negative status. One of the most common experiences was restricting or avoiding sexual contact. Further to this, participants also told of their experiences of imposing rules on what they did (or did not do) sexually. For instance, participants discussed being the insertive partner during anal sex, as this was associated with less risk and, crucially, more control. Seeking reassurance, which is common among a range of anxiety disorders, was particularly evident. Interestingly, for some participants this behaviour was valued and viewed as being responsible; if they did not seek reassurance from professionals then this, they felt, would have been irresponsible.

Testing for HIV prior to commencing PrEP was associated with psychological discomfort. Participants struggled to tolerate the wait for their result, and this impacted on their functioning. Participants' experiences of HIV testing appear to be like other GBM, who also find it anxiety provoking (Lorenc et al., 2011), although this was amplified.

How do HIV anxious GBM make decisions around initiation of PrEP?

Some participants shared that their motivation for starting PrEP stemmed from their perceived inability to cope with the intensity, pervasiveness, and persistence of HIV anxiety. Participants told of having a lack of trust in condoms and that this ultimately meant they were at perpetual risk of HIV, subjectively. This finding may be made sense of from the cognitive-behavioural model of health anxiety (Salkovskis and Bass, 1997; Warwich and Salkovskis, 1990), which suggests that those with health anxiety experience cognitive biases that lead to over-valued beliefs about the likelihood of events that contribute to illness (i.e., condom failures). Although understandable in the context of how HIV anxiety manifested in this group of participants, it is nonetheless a novel finding.

Furthermore, given that most participants were often not engaging in sexual behaviour that they enjoyed, such as receptive anal sex, due to anxiety about HIV acquisition, some shared that they were motivated to initiate PrEP to have a more fulfilling sex life. Specifically, they hoped that through the mitigation of their perceived HIV risk – and thus the subsequent HIV anxiety – they would be liberated to engage in sexual behaviours of which they had previously deprived themselves, despite these behaviours often being part of their erotic template. Although previous research has consistently highlighted sexual liberation to be a key motivation for initiating PrEP among GBM, it is usually considered in terms of a preference for condomless anal sex (Garmel and Golub, 2015). However, in the current study, although some participants did report that they wanted to have condomless anal sex, they appeared to be more motivated by being able to engage in sexual activity *with* a condom but *without* HIV anxiety.

The suppression of their sexuality, insofar as restricting sexual activity to avoid HIV, had led to a sense of loss and regret: participants thought that HIV anxiety had held them back from engaging in the sex that they wanted to have and that was commensurate with their

identity as GBM. In turn, especially in the context of those who were highly restricted in their sexual practices and/or who had experienced HIV anxiety for many years, there was a sense of urgency to engage in sexual behaviours that had previously evaded them. In this regard, the motivation for PrEP was a central prop to operationalise the desire to be more sexually expressive and less restrictive. Although not specific to this population or PrEP users, it is a common observation that those who experience anxiety disorders and avoid or restrict to reduce their anxiety can experience sadness and regret with regards to perceived losses accrued because of an anxiety disorder (Bandelow and Michaelis, 2015).

Another cited reason for initiating PrEP among the participants was a desire to be responsible. Specially, in those participants who wanted to actively pursue a more fulfilling sex life, taking PrEP was viewed as an important tool not only to reduce their perceived HIV risk (and thus HIV anxiety), but also to preserve their health and that of others. PrEP was viewed as a pro-social behaviour and was therefore valued – it promoted social rank. As discussed above, some participants experienced anxiety about the possibility of them infecting partners with HIV. In this regard, some viewed taking PrEP as their responsibility to protect others from potential harm that they may pose. Although previous studies, which have not exclusively recruited GMB with HIV anxiety, have reported a desire to protect one's health as a major motivator for taking PrEP, this desire to protect others has not been widely reported (Bistoquet et al., 2021; Gilmore et al., 2013).

The desire among some participants to take PrEP to principally protect others may be conceptualised as something beyond altruistic behaviour. Specially, it is acknowledged that 'inflated responsibility', which is a key cognition domain in obsessive compulsive disorder (OCD) from Morrison and Westbrook (2004), is common across a range of anxiety disorders, including health anxiety (OCCWG, 1997). Inflated responsibility in this regard is defined as "…one has the power to produce or prevent negative outcomes. This results in the person

feeling obligated to take every possible action to prevent the feared consequence …" (Morrison and Westbrook, 2004, p102-103). The notion that inflated responsibility may be a key cognitive feature in those with HIV anxiety has been suggested previously (Margetts, 2013; Scragg, 1995). Within a cognitive-behavioural framework, it is conceivable that these participants may be taking PrEP to 'neutralise' the threat of infecting others and thus extinguishing anxiety.

What impact does PrEP use have on their experience of sex and sexual behaviour?

It was apparent that PrEP facilitated the removal, or a significant reduction, in HIV anxiety, which allowed participants to engage in sexual experiences that had previously been perceived as too risky or anxiety inducing. Participants noted a wide range of changes in their experience of sex and the sexual behaviours that they engaged in. Specifically, most were engaging in sex more frequently and attributed this to a recalibration of what they considered risky and the absence of HIV anxiety. This was cyclical in that the removal of anxiety meant that sex was more enjoyable and therefore they sought out sexual experiences more frequently. Furthermore, there were changes in sexual positioning – some participants shared that they were engaging in receptive anal and oral sex more frequently and deriving greater sexual satisfaction from this. Overall, participants' experience of sex was that it had improved in quality and was now congruent with their erotic templates. There appeared to be concurrent gains in being able to express their sexuality and no longer restrict or subjugate part of themselves.

Whilst this subjective improvement in psychosexual functioning is not specific to GBH who present with HIV anxiety (Collins et al., 2017; Storholm et al., 2017), it is arguably more significant insofar as the level of function *prior* to starting PrEP given the significant impact

of HIV anxiety. In this regard, the subsequent changes in psychosexual functioning experienced by participants may be considered transformative.

Participants shared their experiences of disclosing their use of PrEP to prospective sexual partners and noted that the association between PrEP and high-risk sexual behaviours had led some prospective partners to assume that they wanted to have condomless anal sex. Participants shared that some prospective sexual partners reacted negatively when participants explained that they use condoms and PrEP concurrently. In turn, this had led some participants to not disclose their PrEP use to avoid such conversations. Participants also experienced having to justify their PrEP use when disclosing their use of it, to mitigate negative reactions.

PrEP stigma has been noted since its inception (Calabrease and Underhill, 2015; Grace et al., 2018) and as such there is a strong and well-established narrative that PrEP use is only for those that are high risk among GBM (Dubov et al., 2018) and health care professionals (Mayer et al., 2020). This perception is perhaps maintained by sample characteristics (i.e., high risk behaviour) of those enrolled in clinical trials and subsequent clinical guidelines, such as those issued by the British Association for Sexual Health & HIV (BASHH; 2020). Although a somewhat unsurprising finding, it is important given the increasing prevalence of PrEP use in the GBM community.

Whilst taking PrEP, some participants had experiences of being diagnosed with sexually transmitted infections (STIs). Participants reflected that the impact of an STI is less problematic than HIV. Specifically, the burden of an STI was more related to the inconvenience of having to go to the clinic for treatment, rather than any associated anxiety. Moreover, it was acknowledged that stigma associated with STIs was less pervasive than the stigma associated with HIV. Participants made sense of this by suggesting the short-term nature of most STIs meant it was perceived differently to HIV. This finding is particularly relevant as it may demonstrate that the psychological impact of being diagnosed STI in this

group of participants appeared to be manageable and did not result in in the same cognitive or behavioural patterns associated with HIV anxiety. Furthermore, given that participants are engaging in more sex (some of which is now condomless) there is an increased chance of acquiring STI, as has been demonstrated from observation and epidemiological studies (Morris et al., 2018; Redina et al., 2018).

What impact does PrEP use have on experiences of anxiety?

All participants in the current study reported that PrEP had a positive impact on their experience of HIV anxiety, as well as their overall wellbeing. Specifically, associations between being gay and inevitably acquiring HIV, and sex and danger appeared to weaken. In turn, this may have led to shifts in unhelpful beliefs and cognitions, which served to perpetuate HIV anxiety. Despite this improvement, some participants continued to experience residual and transient episodes of anxiety related to HIV acquisition; although these were less intense than prior to taking PrEP and appeared to lessen over time. This may be explained by positive reinforcement of negative HIV test results in the context of subjectively increased risk (e.g., having sexual contact). In this regard, PrEP may facilitate new experiences in which participants learn to recalibrate their HIV risk and therefore resulting in less anxiety.

Some participants shared their experience of developing new anxieties after starting PrEP, in place of HIV anxiety. Specifically, some participants became anxious that their perceived liberation, facilitated by PrEP, would result in them engaging in risk compensatory behaviours, such as chemsex or risky sexual behaviours. Other participants became anxious about other STIs which were chronic, such as herpes. This evolution of anxiety targets is commonly seen in those with OCD, although the intensity of the symptoms tends to escalate in severity (Sharma and Math, 2019). Whilst for the current participants it appears that some

may experience new anxieties, all reported that these were relatively mild and not associated with becoming acopic, compared to HIV anxiety.

Clinical Implications

Is HIV anxiety the same as health anxiety?

The findings of the current study suggest that the experience of HIV anxiety for GBM is qualitatively different to that of health anxiety. As discussed in the introductory chapter of this thesis, health anxiety is the most widely used clinical term that refers to diagnostic classification of illness anxiety disorder (Diagnostic and Statistical Manual of Mental Disorders, 5th Edition; APA, 2013) and hypochondriasis (International Statistical Classification of Diseases and Health Related Problems, 10th Revisions, 5th Edition; ICD-10; WHO, 2016), which are used to conceptualise HIV anxiety in clinical populations. However, neither of these diagnostic classifications adequately capture the experiences HIV anxiety among GBM.

Specifically, the DSM V diagnostic criteria for illness anxiety disorder states that: "There is a high level of anxiety about health, and the individual is easily alarmed about personal health status" (DSM V; APA, 2013). Whilst some participants did allude to experiencing more global anxiety regarding their health, most experienced anxiety that was confined to HIV. Despite this, the stipulated criterion does go some way to capturing the experiences of GBM presenting with HIV anxiety, especially regarding the presence of "excessive health-related behaviours" (e.g., repeatedly checking body for rashes/signs of seroconversion) and the exhibition of "maladaptive avoidance" (e.g., avoiding sex).

The ICD-10, which is the diagnostic system most used in the NHS (Clark et al., 2017), diagnostic criteria for hypochondriasis appears to be even less of a 'fit' for the experiences of HIV anxious GBM. Specifically, the criterion states that the individual must have "[a] persistent belief in the presence of a least one serious physical illness underlying the presenting

symptom or symptoms, even though repeated investigations and examinations have identified no adequate explanation …" and "[a] persistent refusal to accept the advice and reassurance of several different doctors that there is no physical illness or abnormality underlying the symptoms." Although some participants did share their experience of misinterpreting physical symptoms and attributing these to HIV infection, the belief that these where a sign of HIV was quashed when they received a negative HIV result. Despite this, HIV anxiety appeared to be most commonly cyclical among GBM (as opposed to consistently persistent, which is common in hypochondriasis).

The validity of psychiatric diagnoses is widely contested, especially within clinical psychology (Jablensky, 2016). It is important to note that although this study is highlighting that the current diagnostic classifications are perhaps not fit for purpose, as applied to the experience of HIV anxiety in GBM, it is not suggesting that HIV anxiety should be considered a phenomenon that would benefit from its own diagnostic classification. Moreover, given the marginalisation that GBM already face, it is conceivable that pathologising their experience further could serve to perpetuate stigma and, in turn, be of detriment to their mental health. However, it is important to consider the fit of diagnostic classifications that are used to capture the experiences of GBM with HIV anxiety. Specifically, diagnostic classification is often used in conjunction with psychological theories and models which inform treatment protocols (National Collaborating Centre for Mental Health, 2020). This is especially true in primary care services, where the majority of GBM presenting with HIV anxiety would likely either seek treatment or be referred. In England, psychological therapies in primary care are delivered by Improving Access to Psychological Therapies (IAPT) services.

Patients who attend IAPT with HIV anxiety would most likely have their difficulties conceptualised and treated within the CBT health anxiety model (Warwick and Salkovskis, 1990) and the corresponding treatment protocol. This study argues that this would impoverish

the effectiveness of the psychological treatment offered. Specifically, it would not target central clinical themes that are evident in this population, such as shame or the perpetual nature of HIV anxiety given their sexual identity. Furthermore, although the health anxiety model does consider developmental information (e.g., homophobia), which may lead to the formation of specific beliefs about oneself, others, and the world, at a largely superficial level, it does not adequately identify the specific psychosocial processes that appear to be implicated in the development of HIV anxiety among GBM, such as internalised homophobia (Newcomb and Mustanski, 2010), stigma-based rejection sensitivity (Pachankis et al., 2018) and concealment of sexual orientation (Pachnakis, 2007). This absence may be seen as rather reductionist and serve to maintain the narrative that the problem is located within the individual, rather than acknowledging the role of psychosocial processes and wider cultural and contextual determinants.

In this regard, it would be a clinical imperative to ensure that those GBM presenting with HIV anxiety are offered a psychological intervention that explores and acknowledges their experience fully, beyond the health anxiety model. Furthermore, given the identification of shame and stigma in the experience, the psychological intervention may benefit from diverging from the health anxiety treatment protocol to include some concepts from compassion focused therapy (Gilbert, 2010a; Gilbert, 2010b).

PrEP as a safety behaviour or an adaptive strategy?

Behavioural avoidance and safety seeking strategies are common features across all anxiety disorders (Strohle et al., 2018). Cognitive behavioural models emphasise the maintaining effects of safety behaviours in anxiety disorders and therefore explicitly advocate targeting them in therapy, either by modification (Parrish et al., 2008; Rachman et al., 2008) or, more commonly, by eradication (Barlow et al., 2004; Salkovskis et al., 1996). Safety

behaviours are frequently associated with functional impairment and are, therefore, often used as a proxy of severity. Consequently, safety behaviours are considered a crucial domain in the description and future classification of anxiety disorder (Shear et al., 2007).

It is acknowledged that clinicians frequently struggle in distinguishing safety behaviours from adaptive coping strategies (Thwaites and Freeston, 2005). This difficulty is compounded by a lack of agreed consensus within the literature as to what constitutes a safety behaviour. In response to this, Helbig-Lang and Petermann (2010) conducted a systematic review on the effects of safety behaviours across anxiety disorders and began their paper by offering a helpful summary of the literature as to how safety behaviours are defined. Specifically, they offer the following summary:

(a) Anxiety-related behaviours can be both adaptative as well as inadequate strategies of coping with emerging anxiety.
(b) In case of real threat, anxiety-driven behaviours are most often adaptive as they serve the survival of the individual.
(c) Safety behaviours are dysfunctional emotional regulation strategies. They can be differentiated from adaptive coping depending both on the situations in which they occur (actual threat versus overrated or no real threat) as well as their function (preventing feared outcomes that are unlikely to happen versus habitual behaviour or behaviour unrelated to the occurrence of anxiety).

Based on this summary, it is conceivable that PrEP use may be classified as a safety behaviour among some HIV anxious GBM who are not objectively at risk of HIV. However, even if GBM consistently use condoms for anal sex they remain collectively ‘at risk’ by their sexual behaviour (i.e., having sex with other men), irrespective of consistent condom use.

Furthermore, there is a significantly greater prevalence of HIV among GBM, compared to their heterosexual counterparts (PHE, 2020) and therefore the potential consequences of a condom failure are quantitatively different. Concordantly, it is conceivable that taking PrEP could be considered an adaptive coping strategy. Indeed, it should be noted that many low risk GBM who are not HIV anxious choose to use PrEP. In the absence of anxiety, their motives – to keep themselves and others safe by preserving their HIV negative status – would seem more like a community adaptive coping strategy than a safety behaviour. In any case, determining the function of taking PrEP is a clinical imperative.

Another important consideration is the assumption that safety behaviours universally result in functional impairment. In the current study, PrEP use was transformational and was experienced as a tool that did not *impede* functioning but *facilitated* functioning (i.e., psychosexual functioning). This finding accords with emerging evidence that safety behaviours, far from being universally unproductive or unhelpful, may even be helpful in the management of anxiety disorders (Rachman et al., 2008). While evidence on inclusion of safety behaviours in the treatment of health anxiety appears to be absent, there are studies, albeit with inconsistent results (Helbig-Lang and Petermann, 2010), that have evaluated the effects of promoting certain safety behaviours in similar disorders, such as OCD (Abramowitz et al., 2001) and panic disorder (Campbell-Sills et al., 2006). In a review, four out of five studies showing positive effects of safety behaviours focused on specific phobias, and specifically on phobias assumed to be biologically prepared. It is hypothesised that the positive effects of safety behaviours in exposure therapy may stem from a predominantly biological vulnerability, suggesting different mechanisms of action and change, compared to other anxiety disorders (Helbig-Lang and Petermann, 2010). HIV anxiety, unlike specific phobias, is characterised by various fears, some of which are not related to the virus itself, but rather the stigma and perceived loss of social rank that may ensue if the infection is acquired. It is

therefore unclear as to whether using PrEP in conjunction with psychological therapy for HIV anxiety would yield superior results compared to taking PrEP or engaging in psychological therapy in isolation.

The results of the current study do raise an ethical dilemma for clinicians and psychological therapists. Specifically, if conceptualised as a safety behaviour then clinicians and psychological therapists may have a duty to discourage PrEP use in the context of HIV anxiety, and instead prioritise psychological therapy. Despite this, the experiences of the GMB in this study do not demonstrate the impact of PrEP on the maintenance and exacerbation of anxiety, through negative reinforcement, which is the central tenet as to why safety behaviours are considered unhelpful (Salkovskis et al., 1997, 2003). This thesis would therefore argue that the emerging phenomenon of low risk GBM, including those who are HIV anxious, choosing to use PrEP may be best conceptualised as a community adaptive coping strategy, as a legacy of the HIV epidemic that is felt so acutely by this population. As such, clinicians and psychological therapists may need to reconsider the assumption that PrEP is a safety behaviour and be open, albeit tentatively, to its utility in HIV anxious GBM.

PrEP use in low risk GBM?

Irrespective of whether clinicians and psychological therapists endorse PrEP use in this population or not, PrEP continues to be widely available from non-NHS sources. It is therefore likely that its use in this population will continue. This scenario appears to be even more likely in the context of the results of this thesis, in which all the participants reported a positive experience overall. It is therefore important that this population are continued to be afforded PrEP monitoring as part of their NHS care, irrespective of the source of the medication, to ensure optimal safety. Although PrEP monitoring was available in most clinics for those self-sourcing, this was in the context of it not being available through the NHS. In turn, it is unclear whether there will be universal access to monitoring as PrEP is now commissioned for routine

use on the NHS. It is conceivable that PrEP monitoring will only be available to those who are prescribed PrEP via an NHS clinic, with prescribing being informed by the British HIV Association/British Association of Sexual Health & HIV (BASHH/BHIVA, 2018) guidelines on the use of PrEP. It is therefore important that policy decision makers continue to be aware that PrEP-users may continue to access PrEP from non-NHS sources when making commission decisions.

The PrEP guidance states that PrEP should only be prescribed in the context of someone being objectively high risk. It is therefore likely that this population will need to embellish their sexual health history to meet the criteria to obtain PrEP on the NHS. Seven of the participants obtained PrEP through the IMPACT trial, which had similar inclusion criteria as the BASHH/BHIVA guidelines, suggesting that participants were required to embellish their sexual health histories and/or that clinicians were applying the criteria liberally. This study highlights the dilemmas facing clinicians – both physicians and psychological practitioners – in balancing the apparent benefits conferred by PrEP use in this population with the potential psychological and physical risks that may result from using PrEP in objectively low risk people belonging to an 'at-risk' group such GBM. Although this study offers emerging evidence of the benefits it is also prudent to consider the risks. Specifically, it is also conceivable that inclusion in the PrEP guidelines may perpetuate beliefs, at an individual, community, and population level that GBM are at greater risk of HIV infection than is objectively accurate.

Strengths and Limitations

In pursuit of a robust critique of the current study, the Critical Appraisal Skills Programme (CASP; 2018), which is the most widely recognised appraisal tool for qualitative studies, was used as framework. The results of this appraisal are presented in Appendix X. Below is a discussion on the strengths and limitations of the current study, as identified

through the CASP appraisal procedure. The approach to the methodological critique is informed by the qualitative study design and its epistemological position (i.e., critical realist).

Experiences of HIV anxious GBM using PrEP

The current research is unique in exploring the experiences of GBM who are (or where) HIV anxious and are using PrEP. Previous research has exclusively focused on high-risk GBM's experience of PrEP with the aims and research questions usually focused on efficacy of PrEP in reducing HIV (Molina et al., 2015; McCormack et al., 2016), risk compensation or barriers to update in high-risk groups (Rendina et al., 2018). Although there is research highlighting the psychological impact of PrEP, this only includes participants whom PrEP is traditionally aimed at (Hojilla et al., 2016). As such, the current study adds rich qualitative data about lived experiences, rather than dominant quantification and correlations. In particular, the current study highlights the lived experiences of HIV anxious GBM, who are often excluded from PrEP research because of their low-risk status. Despite this, this thesis does not presume to represent a comprehensive or definitive account of the experiences of HIV anxious GBM using PrEP. This naturally has limitations, but the findings nonetheless contribute to understanding and highlight the need for further research with this group.

Study Sample

The sample size for the current study (N=10) was within normal parameters, with the suggested range being 6 – 10 participants (Flick, 2008). A total of 22 participants volunteered to participate in the current study (with 12 participants not meeting the criteria for HIV anxiety), suggesting that the recruitment strategy was relatively well conceived. However, there remains scope for recruitment improvements. Specifically, participants were recruited from NHS clinics and were therefore sourcing PrEP through clinical trials or NHS

subsidised private prescriptions (e.g., PrEP Shop) and thus engaged in the recommended monitoring. I formulated that given the participants who were included in the current were highly educated (8 out of 10 had achieved a postgraduate qualification), they may have been more able to engage with information regarding clinical trials and therefore less likely to be self-sourcing online. The experience of self-sourcing PrEP may be qualitatively different from those included in the current sample.

Participant's age ranged from 23 to 61 years. Therefore, the sample included was multigenerational. This is particularly important given that the generational experiences of being gay (Grierson et al., 2005) and HIV (Hunt et al., 2019) are inevitably different, given the ever-changing socio-political context. Furthermore, the sample only included gay men – although the inclusion criteria did not specify sexual orientation, just behaviour – with no representation of bisexual men. Bisexuality is often stigmatised in both the heteronormative society and the gay community (Callis, 2003; Eliason, 2000).

It was noted from the outset of the study that recruitment of those who identify as BAME would be important, as this group experience unique barriers in accessing sexual health care (Witzel et al., 2019). To mitigate this, the study sites included several clinics situated within south east London (serving predominantly BAME communities). Despite this, none of the participants identified as black, highlighting a potential issue with the recruitment strategy. Furthermore, a central thrust of the argument in this thesis is the cumulative nature of minority stress and how this impact on mental health (e.g., development of HIV anxiety) (Meyer, 2003). It is therefore conceivable that GBM who are a racial minority may be especially vulnerable to poorer mental health outcomes (Balsam et al., 2011). Furthermore, there is growing evidence to suggest that PrEP outcomes are worse among black GBM vs. white GBM (Snowden et al., 2014; Liu et al., 2016). It is therefore

crucial that the results of this research may not adequately capture the experiences of HIV anxious black GBM who are using PrEP.

HIV Anxiety Classification

As highlighted throughout this thesis, the phenomenon of HIV anxiety is relatively poorly understood and therefore conceptualisation – especially prior to analysing the results – is challenging. In the current study, the DSM-V illness anxiety disorder (APA, 2013) was used as proxy for HIV anxiety, given that the experience of HIV anxiety maps onto this anxiety disorder most closely vs. that of hypochondriasis (WHO, 2016). The clinical interview (which was incorporated into the semi-structured interview) was used to illicit 'symptoms' of illness anxiety disorder, as related to HIV anxiety. In conjunction with this, participants were asked to complete the Health Anxiety Inventory (HAI-18; Salkovskis et al., 2002). This proved problematic for various reasons. Firstly, asking participants retrospectively as to the presence and nature of HIV anxiety is somewhat unreliable, especially given that anxiety symptoms tend to wax and wane but tend to persist long-term. In turn, participants ability to convey their experience of HIV anxiety may have been diminished. Secondly, although the HAI-18 is the most widely utilised psychological measure for health anxiety, which is used routinely with those accessing IAPT services (National Collaborating Centre for Mental Health, 2020), it is specifically designed to illicit symptoms pertaining to hypochondriasis and not illness anxiety disorder and proved to be an inappropriate selection.

Interpretivist Paradigm

A critical realist approach was a strength of the current study in comparison to previous research into the experiences of PrEP use. Such emphasis on positivist

epistemology in previous research is understandable, especially given PrEP is conceived, first and foremost, as a biomedical intervention. However, psychological research has been criticised for reducing human experiences, and, moreover, leading to policies which prioritise technocratic objectivity at the expense of meaningful social improvement (Fischer, 1998; Darlaston-Jones, 2007). This is perhaps best represented by the fact that GBM continue to be disproportionately affected by HIV and psychological distress, which is often made sense of through diagnostic criteria, despite an abundance of positivist research highlighting these inequalities. An interpretivist epistemology led to the current study incorporating the experiences of GBM who were HIV-anxious beyond the quantitative data. Furthermore, where there has been qualitative exploration into the experiences of PrEP, this has not incorporated those who are deemed objectively low risk and experience distress in the form of HIV anxiety. Thus, applying an interpretivist paradigm to the experiences of these GBM provides further subjective understanding of both HIV anxiety and PrEP use.

Future Research

The role of minority stress (Meyers, 2003) and its associated psychosocial process (e.g., internalised homophobia) have been empirically demonstrated to mediate the expression of mental health difficulties among GBM. Whilst it is conceivable that these processes are implicated in the development of HIV anxiety among GBM (and this is supported by the current study), there needs to be more research to test this hypothesis. Specifically, as Odets (1995) and Scragg (1995) pointed out in their respective papers on the phenomenon, not all GBM go onto develop HIV anxiety. Thus, critical questions requiring attention: Why do only some GBM go onto to develop HIV anxiety? Is it solely due to experiences of minority stress and its associated psychosocial processes? Improving our knowledge and understanding of this phenomenon appears to be fundamental.

Earlier in this chapter, the issues pertaining to the diagnostic criteria being used to 'capture' HIV were discussed. It is evident that there is little beyond anecdotal reports that describe the hallmarks of HIV anxiety, among GBM, in its entirety. Specifically, whilst some of the dominant cognitive-behaviour models of anxiety disorders do offer some explanatory components towards the experience of HIV anxiety, none of these adequately offer a sufficiently comprehensive model, especially in relation to the psychosocial processes related to minority stress. As such, future research would benefit from focusing on development of a theoretical and clinical model of HIV anxiety (not diagnostic criteria), among GBM, to aid psychological formulations. This would, in turn, help clinicians plan more effective interventions and hopefully improve clinical outcomes.

There remains a critical question as to whether PrEP is efficacious as an intervention for HIV anxiety among GBM. This answer to the question may be contributed to in various ways. For example, it may be prudent to ascertain clinicians view on prescribing PrEP in this context. Based on how PrEP was accessed by the current participants, there may be positive views among clinicians about the individual and community benefits of prescribing PrEP in this context. In any case, future research would benefit from engaging with a larger sample in the medium and long-term to determine the risks and benefits, both clinical (i.e., risk compensation) and psychological (i.e., anxiety symptoms).

Final Reflections

Conducing this research has had a profound impact on me. Revisiting the experiences of HIV anxiety was challenging. Not only was it difficult – and at times quite triggering – hearing the psychological pain these men had been in, given my own personal experiences; but it also led me to question the psychological theories and models we use to conceptualise and intervene with this phenomenon. Prior to embarking on this study, I had not quite grasped the

toxicity of homophobia and the deleterious effects on GBM. I suspect this is because homophobia is so insidious and often subtle. I notice more now than before but I am unsure if 'mainstream' clinicians would have similar insights or reflections? If not (which I suspect to be the case) then I consider this a problem within the psychological professions.

I am conscious that the study sample is relatively small, and it would not be clinically or methodologically appropriate to generalise the findings and declare that PrEP is a magic pill that will mute HIV anxiety in GBM. That said, I do believe that PrEP may have a role in helping GBM (both at an individual and community level) to overcome anxiety related to HIV. As such, I genuinely hope that clinicians will remain open minded in its deployment. I will be taking up my first qualified post in HIV and Sexual Health and hope that I can continue this conversation and perhaps agitate for further research.

I have decided to end this thesis by sharing a poem that I have written, which is inspired by my own and the participants experiences of HIV anxiety. I hope the poem conveys the shame that I and they have felt and alludes to that this experience does not need to keep happening.

Relentless

The heat rising
From my stomach to my head.
Doom, dread, dead
There is a storm raging in my head.

Why did I do it?
Because you're stupid
An impending lesson that is stern
You're going to learn!

The invasion in my body is taking hold
Virus swirling around my veins
Seeding my lymph nodes
Obsessing over transmission modes

It's a rash
It's a lesion
Seroconversion is feared
I was the one that steered

I'm tainted and broken
(More than before)
I cannot stop checking
This is my own reckoning

Begging for reassurance
Unable to focus
Incapacitated by the fear
They look back at me from the rear

I've never felt worse
Consumed by the velocity of living
Yet unable to survive
The seed of doubt thrives

It's boiled
The balance has tipped
and it's now test time
I wait in line

I'm begging for mercy
I'll be good from now on
This will be the last time
Oh.. I'm fine

If only this didn't keep happening…

REFERENCES

First Report of AIDS. (n.d.). Retrieved May 14, 2021, from http://www.cdc.gov/mmwr.

(No Title). (n.d.). Retrieved May 14, 2021, from https://www.cdc.gov/mmwr/pdf/wk/mm5021.pdf

RARE CANCER SEEN IN 41 HOMOSEXUALS - The New York Times. (n.d.). Retrieved May 14, 2021, from https://www.nytimes.com/1981/07/03/us/rare-cancer-seen-in-41-homosexuals.html

NEW HOMOSEXUAL DISORDER WORRIES HEALTH OFFICIALS - The New York Times. (n.d.). Retrieved May 14, 2021, from https://www.nytimes.com/1982/05/11/science/new-homosexual-disorder-worries-health-officials.html

Debunking Patient Zero | Maclean's | MAY 2019. (n.d.). Retrieved May 14, 2021, from https://archive.macleans.ca/article/2019/5/1/debunking-patient-zero

Acquired immunodeficiency syndrome - An assessment of the present situation in the world: Memorandum from a WHO meeting. (1984). *Bulletin of the World Health Organization*, *62*(3), 419–432. /pmc/articles/PMC2536320/?report=abstract

Current Trends Update on Acquired Immune Deficiency Syndrome (AIDS) --United States. (n.d.). Retrieved May 14, 2021, from https://www.cdc.gov/mmwr/preview/mmwrhtml/00001163.htm

John 11:1-44 NIV - The Death of Lazarus - Now a man named - Bible Gateway. (n.d.). Retrieved May 14, 2021, from https://www.biblegateway.com/passage/?search=John 11:1-44&version=NIV

HIV in the UK 2016 report. (2016). www.facebook.com/PublicHealthEngland

Home – PrEPWatch. (n.d.). Retrieved May 14, 2021, from https://www.prepwatch.org/

Expanded PrEP Implementation in Communities (EPIC-NSW) | Kirby Institute. (n.d.). Retrieved May 14, 2021, from https://kirby.unsw.edu.au/project/epic-nsw

National Aids Trust -v- NHS England | Courts and Tribunals Judiciary. (2016). https://www.judiciary.uk/judgments/national-aids-trust-v-nhs-england/

Abramowitz, J. S., Deacon, B. J., & Valentiner, D. P. (2007). The short health anxiety inventory: Psychometric properties and construct validity in a non-clinical sample. *Cognitive Therapy and Research*, *31*(6), 871–883. https://doi.org/10.1007/s10608-006-9058-1

Abramowitz, J. S., Tolin, D. F., & Street, G. P. (2001). Paradoxical effects of thought suppression: A meta-analysis of controlled studies. *Clinical Psychology Review*, *21*(5), 683–703. https://doi.org/10.1016/S0272-7358(00)00057-X

Ackerly, B., & True, J. (2008). Reflexivity in practice: Power and ethics in feminist research on international relations. *International Studies Review*, *10*(4), 693–707. https://doi.org/10.1111/j.1468-2486.2008.00826.x

Adam, B. D., Husbands, W., Murray, J., & Maxwell, J. (2005). AIDS optimism, condom fatigue, or self-esteem? Explaining unsafe sex among gay and bisexual men. *Journal of Sex Research*, *42*(3), 238–248. https://doi.org/10.1080/00224490509552278

American Psychiatric Association. (2013). *Diagnostic and Statistical Manual of Mental Disorders*. American Psychiatric Association. https://doi.org/10.1176/appi.books.9780890425596

Arribas, J. R., Pozniak, A. L., Gallant, J. E., DeJesus, E., Gazzard, B., Campo, R. E., Chen, S. S., McColl, D., Holmes, C. B., Enejosa, J., Toole, J. J., & Cheng, A. K. (2008). Tenofovir disoproxil fumarate, emtricitabine, and efavirenz compared with zidovudine/lamivudine and efavirenz in treatment-naive patients: 144-Week analysis.

Journal of Acquired Immune Deficiency Syndromes, *47*(1), 74–78. https://doi.org/10.1097/QAI.0b013e31815acab8

Attride-Stirling, J. (2001). Thematic networks: An analytic tool for qualitative research. *Qualitative Research*, *1*(3), 385–405. https://doi.org/10.1177/146879410100100307

Auerbach, D. M., Darrow, W. W., Jaffe, H. W., & Curran, J. W. (1984). Cluster of cases of the acquired immune deficiency syndrome. Patients linked by sexual contact. *The American Journal of Medicine*, *76*(3), 487–492. https://doi.org/10.1016/0002-9343(84)90668-5

Auerbach, J. D., & Hoppe, T. A. (2015). Beyond "'getting drugs into bodies'": Social science perspectives on pre-exposure prophylaxis for HIV. In *Journal of the International AIDS Society* (Vol. 18, Issue 4Suppl 3). International AIDS Society. https://doi.org/10.7448/IAS.18.4.19983

Babiker, A., Darby, S., De Angelis, D., Ewart, D., Porter, K., Beral, V., Darbyshire, J., Day, N., & Gill, N. (2000). Time from HIV-1 seroconversion to AIDS and death before widespread use of highly-active antiretroviral therapy: a collaborative re-analysis. *Lancet*, *355*(9210), 1131–1137. https://doi.org/10.1016/S0140-6736(00)02061-4

Balán, I. C., Carballo-Diéguez, A., Ventuneac, A., Remien, R. H., Dolezal, C., & Ford, J. (2013). Are HIV-negative men who have sex with men and who bareback concerned about HIV infection? Implications for HIV risk reduction interventions. *Archives of Sexual Behavior*, *42*(2), 279–289. https://doi.org/10.1007/s10508-011-9886-2

Balsam, K. F., Molina, Y., Beadnell, B., Simoni, J., & Walters, K. (2011). Measuring Multiple Minority Stress: The LGBT People of Color Microaggressions Scale. *Cultural Diversity and Ethnic Minority Psychology*, *17*(2), 163–174. https://doi.org/10.1037/a0023244

Bandelow, B., & Michaelis, S. (2015). Epidemiology of anxiety disorders in the 21st century. *Dialogues in Clinical Neuroscience*, *17*(3), 327–335. https://doi.org/10.31887/dcns.2015.17.3/bbandelow

Barbour, R. S. (2001). Checklists for improving rigour in qualitative research: A case of the tail wagging the dog? In *British Medical Journal* (Vol. 322, Issue 7294, pp. 1115–1117). BMJ Publishing Group. https://doi.org/10.1136/bmj.322.7294.1115

Barlow, D. H., Allen, L. B., & Choate, M. L. (2004). Toward a unified treatment for emotional disorders. *Behavior Therapy*, *35*(2), 205–230. https://doi.org/10.1016/S0005-7894(04)80036-4

Barré-Sinoussi, F., Chermann, J. C., Rey, F., Nugeyre, M. T., Chamaret, S., Gruest, J., Dauguet, C., Axler-Blin, C., Vézinet-Brun, F., Rouzioux, C., Rozenbaum, W., & Montagnier, L. (1983). Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). *Science*, *220*(4599), 868–871. https://doi.org/10.1126/science.6189183

Bergin, M., Wells, J. S. G., & Owen, S. (2010). Relating realist metatheory to issues of gender and mental health. *Journal of Psychiatric and Mental Health Nursing*, *17*(5), 442–451. https://doi.org/10.1111/j.1365-2850.2010.01559.x

Bérubé, A. (2003). The history of gay bathhouses. *Journal of Homosexuality*, *44*(3–4), 33–53. https://doi.org/10.1300/J082v44n03_03

Bisson, J., & Andrew, M. (2007). Psychological treatment of post-traumatic stress disorder (PTSD). In *Cochrane Database of Systematic Reviews* (Issue 3). John Wiley and Sons Ltd. https://doi.org/10.1002/14651858.CD003388.pub3

Bistoquet, M., Makinson, A., Tribout, V., Perrollaz, C., Bourrel, G., Reynes, J., & Oude Engberink, A. (2021). Pre-exposure prophylaxis makes it possible to better live one's sexuality and guide men who have sex with men towards a responsible approach to their

health: a phenomenological qualitative study about primary motivations for PrEP. *AIDS Research and Therapy*, *18*(1), 1–8. https://doi.org/10.1186/s12981-020-00327-7

Black, I. (2006). The presentation of interpretivist research. *Qualitative Market Research: An International Journal*, *9*(4), 319–324. https://doi.org/10.1108/13522750610689069

Blaikie, N. (2007). *Approaches to Social Enquiry: Advancing Knowledge*. Polity Press. https://books.google.co.uk/books?hl=en&lr=&id=a8LAIqk0-nIC&oi=fnd&pg=PR4&dq=Blaikie,+2007&ots=TDLdZpCRCt&sig=9qYDQgICts6JO60wJBXWXpXgdYU#v=onepage&q=Blaikie%2C 2007&f=false

Blair, T. R. (2017). Safe sex in the 1970s: Community practitioners on the Eve of AIDS. In *American Journal of Public Health* (Vol. 107, Issue 6, pp. 872–879). American Public Health Association Inc. https://doi.org/10.2105/AJPH.2017.303704

Blumenthal, J., & Haubrich, R. H. (2014). Will risk compensation accompany pre-exposure prophylaxis for HIV? *Virtual Mentor*, *16*(11), 909–915. https://doi.org/10.1001/virtualmentor.2014.16.11.stas1-1411

Bond, K. T., Frye, V., Taylor, R., Williams, K., Bonner, S., Lucy, D., Cupid, M., Weiss, L., & Koblin, B. A. (2015). Knowing is not enough: A qualitative report on HIV testing among heterosexual African-American men. *AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV*, *27*(2), 182–188. https://doi.org/10.1080/09540121.2014.963009

Brady, M., Rodger, A., Asboe, D., Cambiano, V., Clutterbuck, D., Desai, M., Field, N., Harbottle, J., Jamal, Z., McCormack, S., Palfreeman, A., Portman, M., Quinn, K., Tenant-Flowers, M., Wilkins, E., & Young, I. (2019). BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP) 2018. *HIV Medicine*, *20*, s2–s80. https://doi.org/10.1111/hiv.12718

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Briggs, C. L. (1986). Learning How to Ask. In *Learning How to Ask*. Cambridge University Press. https://doi.org/10.1017/cbo9781139165990

Brisson, J., Ravitsky, V., & Williams-Jones, B. (2019). Towards an integration of PrEP into a safe sex ethics framework for men who have sex with men. *Public Health Ethics*, *12*(1), 54–63. https://doi.org/10.1093/phe/phy018

Brocki, J. M., & Wearden, A. J. (2006). A critical evaluation of the use of interpretative phenomenological analysis (IPA) in health psychology. *Psychology and Health*, *21*(1), 87–108. https://doi.org/10.1080/14768320500230185

Brodsky, A. (2017). "Rape-Adjacent": Imagining Legal Responses to Nonconsensual Condom Removal. *Columbia Journal of Gender and Law*, *32*(2). https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2954726

Brooks, J. T., Buchacz, K., Gebo, K. A., & Mermin, J. (2012). HIV infection and older Americans: The public health perspective. In *American Journal of Public Health* (Vol. 102, Issue 8, pp. 1516–1526). American Public Health Association. https://doi.org/10.2105/AJPH.2012.300844

Burr, V. (2003). Social constructionism: Second edition. In *Social Constructionism: Second Edition*. Routledge Taylor & Francis Group. https://doi.org/10.4324/9780203694992

Caceres, C. F., & Van Griensven, G. J. P. (1994). Male homosexual transmission of HIV-1. In *AIDS* (Vol. 8, Issue 8, pp. 1051–1061). Lippincott Williams and Wilkins. https://doi.org/10.1097/00002030-199408000-00004

Calabrese, S. K., & Underhill, K. (2015). How stigma surrounding the use of HIV preexposure prophylaxis undermines prevention and pleasure: A call to destigmatize

"truvada whores." In *American Journal of Public Health* (Vol. 105, Issue 10, pp. 1960–1964). American Public Health Association Inc. https://doi.org/10.2105/AJPH.2015.302816

Callis, A. S. (2009). Playing with Butler and Foucault: Bisexuality and queer theory. *Journal of Bisexuality*, *9*(3–4), 213–233. https://doi.org/10.1080/15299710903316513

Campbell-Sills, L., Cohan, S. L., & Stein, M. B. (2006). Relationship of resilience to personality, coping, and psychiatric symptoms in young adults. *Behaviour Research and Therapy*, *44*(4), 585–599. https://doi.org/10.1016/j.brat.2005.05.001

Carballo-Diéguez, A., Balan, I., Dolezal, C., & Mello, M. B. (2012). Recalled sexual experiences in childhood with older partners: A study of Brazilian men who have sex with men and male-to-female transgender persons. *Archives of Sexual Behavior*, *41*(2), 363–376. https://doi.org/10.1007/s10508-011-9748-y

Carballo-Diéguez, A., & Bauermeister, J. (2004). "Barebacking": Intentional condomless anal sex in HIV-risk contexts. Reasons for and against it. *Journal of Homosexuality*, *47*(1), 1–16. https://doi.org/10.1300/J082v47n01_01

Cardo, D. M., Culver, D. H., Ciesielski, C. A., Srivastava, P. U., Marcus, R., Abiteboul, D., Heptonstall, J., Ippolito, G., Lot, F., McKibben, P. S., & Bell, D. M. (1997). A Case–Control Study of HIV Seroconversion in Health Care Workers after Percutaneous Exposure. *New England Journal of Medicine*, *337*(21), 1485–1490. https://doi.org/10.1056/nejm199711203372101

Carlo Hojilla, J., Koester, K. A., Cohen, S. E., Buchbinder, S., Ladzekpo, D., Matheson, T., & Liu, A. Y. (2016). Sexual Behavior, Risk Compensation, and HIV Prevention Strategies Among Participants in the San Francisco PrEP Demonstration Project: A Qualitative Analysis of Counseling Notes. *AIDS and Behavior*, *20*(7), 1461–1469. https://doi.org/10.1007/s10461-015-1055-5

Cass, V. C. (1984). Homosexual identity formation: Testing a theoretical model. *The Journal of Sex Research*, *20*(2), 143–167. https://doi.org/10.1080/00224498409551214

Charmaz, K. (2000). Grounded theory : objectivist and constructivist methods . In K. Norman, S. Denzin, & Yvonna S (Eds.), *Handbook of qualitative research* (2nd ed., pp. 509–535). Sage. https://www.worldcat.org/title/grounded-theory-objectivist-and-constructivist-methods/oclc/174103105

Churchill, D. R., De Cock, K. M., & Miller, R. F. (1994). Feigned HIV infection/AIDS: Malingering and Munchausen's syndrome. *Sexually Transmitted Infections*, *70*(5), 314–316. https://doi.org/10.1136/sti.70.5.314

Clark, D. (2004). *Cognitive-behavioral therapy for OCD*. Guilford Press. https://psycnet.apa.org/record/2004-16373-000

Clark, L. A., Cuthbert, B., Lewis-Fernández, R., Narrow, W. E., & Reed, G. M. (2017). Three Approaches to Understanding and Classifying Mental Disorder: ICD-11, DSM-5, and the National Institute of Mental Health's Research Domain Criteria (RDoC). *Psychological Science in the Public Interest*, *18*(2), 72–145. https://doi.org/10.1177/1529100617727266

Cochran, S. D. (2001). Emerging Issues in Research on Lesbians' and Gay Men's Mental Health: Does Sexual Orientation Really Matter? *American Psychologist*, *56*(11), 931–947. https://doi.org/10.1037/0003-066X.56.11.931

Cochran, S. D., Sullivan, J. G., & Mays, V. M. (2003). Prevalence of mental disorders, psychological distress, and mental health services use among lesbian, gay, and bisexual adults in the United States. *Journal of Consulting and Clinical Psychology*, *71*(1), 53–61. https://doi.org/10.1037/0022-006X.71.1.53

Cohen, C. J., & Stein, T. S. (1986). Reconceptualizing Individual Psychotherapy with Gay Men and Lesbians. In *Contemporary Perspectives on Psychotherapy with Lesbians and Gay Men* (pp. 27–54). Springer US. https://doi.org/10.1007/978-1-4757-9832-6_3

Cohen, C. J., & Stein, T. S. (1986). Reconceptualizing Individual Psychotherapy with Gay Men and Lesbians. In *Contemporary Perspectives on Psychotherapy with Lesbians and Gay Men* (pp. 27–54). Springer US. https://doi.org/10.1007/978-1-4757-9832-6_3

Cohen, M. S., Chen, Y. Q., McCauley, M., Gamble, T., Hosseinipour, M. C., Kumarasamy, N., Hakim, J. G., Kumwenda, J., Grinsztejn, B., Pilotto, J. H. S., Godbole, S. V., Chariyalertsak, S., Santos, B. R., Mayer, K. H., Hoffman, I. F., Eshleman, S. H., Piwowar-Manning, E., Cottle, L., Zhang, X. C., … Fleming, T. R. (2016). Antiretroviral Therapy for the Prevention of HIV-1 Transmission. *New England Journal of Medicine*, *375*(9), 830–839. https://doi.org/10.1056/nejmoa1600693

Cohen, M. S., Chen, Y. Q., McCauley, M., Gamble, T., Hosseinipour, M. C., Kumarasamy, N., Hakim, J. G., Kumwenda, J., Grinsztejn, B., Pilotto, J. H. S., Godbole, S. V., Mehendale, S., Chariyalertsak, S., Santos, B. R., Mayer, K. H., Hoffman, I. F., Eshleman, S. H., Piwowar-Manning, E., Wang, L., … Fleming, T. R. (2011). Prevention of HIV-1 Infection with Early Antiretroviral Therapy. *New England Journal of Medicine*, *365*(6), 493–505. https://doi.org/10.1056/NEJMoa1105243

Collins, S. P., McMahan, V. M., & Stekler, J. D. (2017). The Impact of HIV Pre-exposure Prophylaxis (PrEP) Use on the Sexual Health of Men Who Have Sex with Men: A Qualitative Study in Seattle, WA. *International Journal of Sexual Health*, *29*(1), 55–68. https://doi.org/10.1080/19317611.2016.1206051

Coyer, L., van den Elshout, M. A. M., Achterbergh, R. C. A., Matser, A., Schim van der Loeff, M. F., Davidovich, U., de Vries, H. J. C., Prins, M., Hoornenborg, E., & Boyd, A. (2020). Understanding pre-exposure prophylaxis (PrEP) regimen use: Switching and discontinuing daily and event-driven PrEP among men who have sex with men. *EClinicalMedicine*, *29–30*. https://doi.org/10.1016/j.eclinm.2020.100650

Craske, M. G., Roy-Byrne, P. P., Stein, M. B., Sullivan, G., Sherbourne, C., & Bystritsky, A. (2009). Treatment for anxiety disorders: Efficacy to effectiveness to implementation. *Behaviour Research and Therapy*, *47*(11), 931–937. https://doi.org/10.1016/j.brat.2009.07.012

Cresswell, F., Waters, L., Briggs, E., Fox, J., Harbottle, J., Hawkins, D., Murchie, M., Radcliffe, K., Rafferty, P., Rodger, A., & Fisher, M. (2016). UK guideline for the use of HIV Post-Exposure Prophylaxis Following Sexual Exposure, 2015. *International Journal of STD and AIDS*, *27*(9), 713–738. https://doi.org/10.1177/0956462416641813

Creswell, J., & Piano-Clark, V. (2011). *Designing and Conducting Mixed Methods Research*. Sage. https://us.sagepub.com/en-us/nam/designing-and-conducting-mixed-methods-research/book241842

Crooks, D. L. (2001). The importance of symbolic interaction in grounded theory research on women's health. *Health Care for Woman International*, *22*(1–2), 11–27. https://doi.org/10.1080/073993301300003054

De Vincenzi, I. (1994). A Longitudinal Study of Human Immunodeficiency Virus Transmission by Heterosexual Partners. *New England Journal of Medicine*, *331*(6), 341–346. https://doi.org/10.1056/nejm199408113310601

Dubov, A., Ogunbajo, A., Altice, F. L., & Fraenkel, L. (2019). Optimizing access to PrEP based on MSM preferences: results of a discrete choice experiment. *AIDS Care* -

Psychological and Socio-Medical Aspects of AIDS/HIV, *31*(5), 545–553. https://doi.org/10.1080/09540121.2018.1557590

Durack, D. T. (1981). Opportunistic Infections and Kaposi's Sarcoma in Homosexual Men. *New England Journal of Medicine*, *305*(24), 1465–1467. https://doi.org/10.1056/nejm198112103052408

Eiden, L. E., & Lifson, J. D. (1992). HIV interactions with CD4: a continuum of conformations and consequences. *Immunology Today*, *13*(6), 201–206. https://doi.org/10.1016/0167-5699(92)90154-Y

Eisenberg, A., Bauermeister, J. A., Pingel, E., Johns, M. M., & Santana, M. L. (2011). Achieving safety: Safer sex, communication, and desire among young gay men. *Journal of Adolescent Research*, *26*(5), 645–669. https://doi.org/10.1177/0743558411402342

Eliason, M. (2000). Bi-negativity: The stigma facing bisexual men. *Journal of Bisexuality*, *1*(2–3), 137–154. https://doi.org/10.1300/J159v01n02_05

Evangeli, M., Pady, K., & Wroe, A. L. (2016). Which Psychological Factors are Related to HIV Testing? A Quantitative Systematic Review of Global Studies. *AIDS and Behavior*, *20*(4), 880–918. https://doi.org/10.1007/s10461-015-1246-0

Farley, T. A., Cohen, D. A., & Elkins, W. (2003). Asymptomatic sexually transmitted diseases: The case for screening. *Preventive Medicine*, *36*(4), 502–509. https://doi.org/10.1016/S0091-7435(02)00058-0

Fischer, F. (1998). Beyond empiricism: Policy inquiry in postpositivist perspective. *Policy Studies Journal*, *26*(1), 129–146. https://doi.org/10.1111/j.1541-0072.1998.tb01929.x

Fischl, M. A., Parker, C. B., & Pettinelli, C. (1991). A randomized controlled trial of a reduced daily dose of zidovudine in patients with the acquired immunodeficiency syndrome. *Annals of Internal Medicine*, *114*(SUPPL. 1), 4. https://doi.org/10.1056/nejm199010113231501

Fischl, M. A., Richman, D. D., Grieco, M. H., Gottlieb, M. S., Volberding, P. A., Laskin, O. L., Leedom, J. M., Groopman, J. E., Mildvan, D., Schooley, R. T., Jackson, G. G., Durack, D. T., & King, D. (1987). The Efficacy of Azidothymidine (AZT) in the Treatment of Patients with AIDS and AIDS-Related Complex. *New England Journal of Medicine*, *317*(4), 185–191. https://doi.org/10.1056/NEJM198707233170401

Freedberg, K. A., Losina, E., Weinstein, M. C., Paltiel, A. D., Cohen, C. J., Seage, G. R., Craven, D. E., Zhang, H., Kimmel, A. D., & Goldie, S. J. (2001). The Cost Effectiveness of Combination Antiretroviral Therapy for HIV Disease. *New England Journal of Medicine*, *344*(11), 824–831. https://doi.org/10.1056/nejm200103153441108

Friedman-Kien, A. E. (1981). Disseminated Kaposi's sarcoma syndrome in young homosexual men. *Journal of the American Academy of Dermatology*, *5*(4), 468–471. https://doi.org/10.1016/S0190-9622(81)80010-2

Frost, J. J., & Darroch, J. E. (2008). Factors Associated with Contraceptive Choice and Inconsistent Method Use, United States, 2004. *Perspectives on Sexual and Reproductive Health*, *40*(2), 94–104. https://doi.org/10.1363/4009408

Frost, N., Nolas, S. M., Brooks-Gordon, B., Esin, C., Holt, A., Mehdizadeh, L., & Shinebourne, P. (2014). Pluralism in qualitative research: The impact of different researchers and qualitative approaches on the analysis of qualitative data. *BMJ Open*, *4*(11), 441–460. https://doi.org/10.1177/1468794110366802

Frost, R., Steketee, G., Amir, N., Bouvard, M., Carmin, C., Clark, D. A., Cottraux, J., Eisen, J., Emmelkamp, P., Foa, E., Freeston, M., Hoekstra, R., Kozak, M., Kyrios, M., Ladouceur, R., March, J., McKay, D., Neziroglu, F., Pinard, G., … Yaryura-Tobias, J.

(1997). Cognitive assessment of obsessive-compulsive disorder. *Behaviour Research and Therapy*, *35*(7), 667–681. https://doi.org/10.1016/S0005-7967(97)00017-X

Furman, P. A., Fyfe, J. A., St Clair, M. H., Weinhold, K., Rideout, J. L., Freeman, G. A., Lehrman, S. N., Bolognesi, D. P., Broder, S., & Mitsuya, H. (1986). Phosphorylation of 3'-azido-3'-deoxythymidine and selective interaction of the 5'-triphosphate with human immunodeficiency virus reverse transcriptase. *Proceedings of the National Academy of Sciences of the United States of America*, *83*(21), 8333–8337. https://doi.org/10.1073/pnas.83.21.8333

Furukawa, T. A., Watanabe, N., & Churchill, R. (2007). Combined psychotherapy plus antidepressants for panic disorder with or without agoraphobia. In *Cochrane Database of Systematic Reviews* (Vol. 2007, Issue 1). John Wiley and Sons Ltd. https://doi.org/10.1002/14651858.CD004364.pub2

Galindo, G. R., Walker, J. J., Hazelton, P., Lane, T., Steward, W. T., Morin, S. F., & Arnold, E. A. (2012). Community member perspectives from transgender women and men who have sex with men on pre-exposure prophylaxis as an HIV prevention strategy: Implications for implementation. *Implementation Science*, *7*(1), 1–13. https://doi.org/10.1186/1748-5908-7-116

Gallo, R. C., Salahuddin, S. Z., Popovic, M., Shearer, G. M., Kaplan, M., Haynes, B. F., Palker, T. J., Redfield, R., Oleske, J., Safai, B., White, G., Foster, P., & Markham, P. D. (1984). Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS. *Science*, *224*(4648), 500–503. https://doi.org/10.1126/science.6200936

Gallo, R. C., Sarin, P. S., Gelmann, E. P., Robert-Guroff, M., Richardson, E., Kalyanaraman, V. S., Mann, D., Sidhu, G. D., Stahl, R. E., Zolla-Pazner, S., Leibowitch, J., & Popovic, M. (1983). Isolation of human T-cell leukemia virus in acquired immune deficiency syndrome (AIDS). *Science*, *220*(4599), 865–867. https://doi.org/10.1126/science.6601823

Gamarel, K. E., & Golub, S. A. (2015). Intimacy Motivations and Pre-exposure Prophylaxis (PrEP) Adoption Intentions Among HIV-Negative Men Who Have Sex with Men (MSM) in Romantic Relationships. *Annals of Behavioral Medicine*, *49*(2), 177–186. https://doi.org/10.1007/s12160-014-9646-3

García-Lerma, J. G., Otten, R. A., Qari, S. H., Jackson, E., Cong, M. E., Masciotra, S., Luo, W., Kim, C., Adams, D. R., Monsour, M., Lipscomb, J., Johnson, J. A., Delinsky, D., Schinazi, R. F., Janssen, R., Folks, T. M., & Heneine, W. (2008). Prevention of rectal SHIV transmission in macaques by daily or intermittent prophylaxis with emtricitabine and tenofovir. *PLoS Medicine*, *5*(2), 0291–0299. https://doi.org/10.1371/journal.pmed.0050028

Gilbert, P. (2010). *Compassion focused therapy: Distinctive features*. Routledge/Taylor Francis Group. https://psycnet.apa.org/record/2010-09191-000

Gilbert, P., & Procter, S. (2006). Compassionate mind training for people with high shame and self-criticism: Overview and pilot study of a group therapy approach. In *Clinical Psychology and Psychotherapy* (Vol. 13, Issue 6, pp. 353–379). John Wiley & Sons, Ltd. https://doi.org/10.1002/cpp.507

GILEAD. (2004, August 2). *U.S. FDA Approves Gilead's Truvada, a One-Tablet, Once-a-Day Fixed-Dose Co-Formulation of Viread and Emtriva as Part of HIV Combination*

Therapy. https://www.gilead.com/news-and-press/press-room/press-releases/2004/8/us-fda-approves-gileads-truvada-a-onetablet-onceaday-fixeddose-coformulation-of-viread-and-emtriva-as-part-of-hiv-combination-therapy

Gilmore, H. J., Liu, A., Koester, K. A., Amico, K. R., McMahan, V., Goicochea, P., Vargas, L., Lubensky, D., Buchbinder, S., & Grant, R. (2013). Participant experiences and facilitators and barriers to pill use among men who have sex with men in the iprex pre-exposure prophylaxis trial in san francisco. *AIDS Patient Care and STDs*, *27*(10), 560–566. https://doi.org/10.1089/apc.2013.0116

Glaser, B., & Strauss, A. (1967). *The Discovery of Grounded Theory*. Aldine. https://en.wikipedia.org/wiki/The_Discovery_of_Grounded_Theory

Godin, G., Naccache, H., & Pelletier, R. (2000). Seeking medical advice if HIV symptoms are suspected: Qualitative study of beliefs among HIV-negative gay men. *Canadian Family Physician*, *46*(APR.), 861–868. /pmc/articles/PMC2144804/?report=abstract

Goffman, E. (1963). *Stigma : notes on the management of spoiled identity*. Prentice Hall. https://www.worldcat.org/title/stigma-notes-on-the-management-of-spoiled-identity/oclc/223060

Goldenberg, S. M., Duff, P., & Krusi, A. (2015). Work environments and HIV prevention: a qualitative review and meta-synthesis of sex worker narratives. *BMC Public Health*, *15*(1), 1241. https://doi.org/10.1186/s12889-015-2491-x

Golub, S. A., Fikslin, R. A., Goldberg, M. H., Peña, S. M., & Radix, A. (2019). Predictors of PrEP Uptake Among Patients with Equivalent Access. *AIDS and Behavior*, *23*(7), 1917–1924. https://doi.org/10.1007/s10461-018-2376-y

Golub, S. A., Kowalczyk, W., Weinberger, C. L., & Parsons, J. T. (2010). Preexposure prophylaxis and predicted condom use among high-risk men who have sex with men.

Journal of Acquired Immune Deficiency Syndromes, *54*(5), 548–555. https://doi.org/10.1097/QAI.0b013e3181e19a54

Gonsiorek, J. C. (1988). Mental health issues of gay and lesbian adolescents. *Journal of Adolescent Health Care*, *9*(2), 114–122. https://doi.org/10.1016/0197-0070(88)90057-5

Grace, D., Chown, S. A., Jollimore, J., Parry, R., Kwag, M., Steinberg, M., Trussler, T., Rekart, M., & Gilbert, M. (2014). HIV-negative gay men's accounts of using context-dependent sero-adaptive strategies. *Culture, Health and Sexuality*, *16*(3), 316–330. https://doi.org/10.1080/13691058.2014.883644

Grace, D., Jollimore, J., MacPherson, P., Strang, M. J. P., & Tan, D. H. S. (2018). The Pre-Exposure Prophylaxis-Stigma Paradox: Learning from Canada's First Wave of PrEP Users. *AIDS Patient Care and STDs*, *32*(1), 24–30. https://doi.org/10.1089/apc.2017.0153

Grant, R. M., Anderson, P. L., McMahan, V., Liu, A., Amico, K. R., Mehrotra, M., Hosek, S., Mosquera, C., Casapia, M., Montoya, O., Buchbinder, S., Veloso, V. G., Mayer, K., Chariyalertsak, S., Bekker, L. G., Kallas, E. G., Schechter, M., Guanira, J., Bushman, L., … Glidden, D. V. (2014). Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: A cohort study. *The Lancet Infectious Diseases*, *14*(9), 820–829. https://doi.org/10.1016/S1473-3099(14)70847-3

Grant, R. M., Lama, J. R., Anderson, P. L., McMahan, V., Liu, A. Y., Vargas, L., Goicochea, P., Casapía, M., Guanira-Carranza, J. V., Ramirez-Cardich, M. E., Montoya-Herrera, O., Fernández, T., Veloso, V. G., Buchbinder, S. P., Chariyalertsak, S., Schechter, M.,

Bekker, L.-G., Mayer, K. H., Kallás, E. G., … Glidden, D. V. (2010). Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men. *New England Journal of Medicine*, *363*(27), 2587–2599. https://doi.org/10.1056/nejmoa1011205

Green, E. C., Halperin, D. T., Nantulya, V., & Hogle, J. A. (2006). Uganda's HIV prevention success: The role of sexual behavior change and the national response. In *AIDS and Behavior* (Vol. 10, Issue 4, pp. 335–346). AIDS Behav. https://doi.org/10.1007/s10461-006-9073-y

Grierson, J., & Smith, A. M. A. (2006). In from the outer: Generational differences in coming out and gay identity formation. *Journal of Homosexuality*, *50*(1), 53–70. https://doi.org/10.1300/J082v50n01_03

Grix, J. (2019). *The Foundations of Research* (3rd ed.). Red Globe Press. https://www.macmillanihe.com/page/detail/The-Foundations-of-Research/?K=9781352002003

Grohskopf, L. A., Chillag, K. L., Gvetadze, R., Liu, A. Y., Thompson, M., Mayer, K. H., Collins, B. M., Pathak, S. R., O'hara, B., Ackers, M. L., Rose, C. E., Grant, R. M., Paxton, L. A., & Buchbinder, S. P. (2013). Randomized trial of clinical safety of daily oral tenofovir disoproxil fumarate among HIV-uninfected men who have sex with men in the United States. *Journal of Acquired Immune Deficiency Syndromes*, *64*(1), 79–86. https://doi.org/10.1097/QAI.0b013e31828ece33

Hamilton, J. G. (1995). Needle phobia: a neglected diagnosis. *Journal of Family Practice*, *41*(2), 169–176. https://go.gale.com/ps/i.do?p=AONE&sw=w&issn=00943509&v=2.1&it=r&id=GALE%7CA17276569&sid=googleScholar&linkaccess=fulltext

Hatzenbuehler, M. L. (2009). How Does Sexual Minority Stigma “Get Under the Skin”? A Psychological Mediation Framework. *Psychological Bulletin*, *135*(5), 707–730. https://doi.org/10.1037/a0016441

Health England, P. (2019). *HIV in the UK: Towards Zero HIV transmissions by 2030*. www.facebook.com/PublicHealthEngland

Health England, P. (2017). *Towards elimination of HIV transmission, AIDS and HIV-related deaths in the UK*. www.facebook.com/PublicHealthEngland

Helbig-Lang, S., & Petermann, F. (2010). Tolerate or eliminate? A systematic review on the effects of safety behavior across anxiety disorders. In *Clinical Psychology: Science and Practice* (Vol. 17, Issue 3, pp. 218–233). John Wiley & Sons, Ltd. https://doi.org/10.1111/j.1468-2850.2010.01213.x

HIV i-Base. (2019). *UK Guide to PrEP* . https://i-base.info/uk-guide-to-prep-november-2019/

Homer, B. D., Solomon, T. M., Moeller, R. W., Mascia, A., DeRaleau, L., & Halkitis, P. N. (2008). Methamphetamine Abuse and Impairment of Social Functioning: A Review of the Underlying Neurophysiological Causes and Behavioral Implications. *Psychological Bulletin*, *134*(2), 301–310. https://doi.org/10.1037/0033-2909.134.2.301

Hoornenborg, E., Prins, M., Achterbergh, R. C. A., Woittiez, L. R., Cornelissen, M., Jurriaans, S., Kootstra, N. A., Anderson, P. L., Reiss, P., de Vries, H. J. C., Prins, J. M., & de Bree, G. J. (2017). Acquisition of wild-type HIV-1 infection in a patient on pre-exposure prophylaxis with high intracellular concentrations of tenofovir diphosphate: a case report. *The Lancet HIV*, *4*(11), e522–e528. https://doi.org/10.1016/S2352-3018(17)30132-7

Hosek, S. G., Rudy, B., Landovitz, R., Kapogiannis, B., Siberry, G., Rutledge, B., Liu, N., Brothers, J., Mulligan, K., Zimet, G., Lally, M., Mayer, K. H., Anderson, P., Kiser, J.,

Rooney, J. F., & Wilson, C. M. (2017). An HIV Preexposure Prophylaxis Demonstration Project and Safety Study for Young MSM. *Journal of Acquired Immune Deficiency Syndromes*, *74*(1), 21–29. https://doi.org/10.1097/QAI.0000000000001179

Hudson, L. A., & Ozanne, J. L. (1988). Alternative Ways of Seeking Knowledge in Consumer Research. *Journal of Consumer Research*, *14*(4), 508. https://doi.org/10.1086/209132

Hunot, V., Churchill, R., Teixeira, V., & Silva De Lima, M. (2007). Psychological therapies for generalised anxiety disorder. In *Cochrane Database of Systematic Reviews* (Vol. 2007, Issue 1). John Wiley and Sons Ltd. https://doi.org/10.1002/14651858.CD001848.pub4

Hunt, G., Wang, L., Bacani, N., Card, K., Sereda, P., Lachowsky, N., Roth, E., Hogg, R., Moore, D., & Armstrong, H. (2019). Generational differences in sexual behaviour and partnering among gay, bisexual, and other men who have sex with men. *Canadian Journal of Human Sexuality*, *28*(2), 215–225. https://doi.org/10.3138/cjhs.2019-0014

Husserl, E. (2001). *Logical Investigations* (Vol. 1). Routledge. https://www.routledge.com/Logical-Investigations-Volume-1/Husserl-Moran/p/book/9780415241892

Jablensky, A. (2016). Psychiatric classifications: Validity and utility. *World Psychiatry*, *15*(1), 26–31. https://doi.org/10.1002/wps.20284

Jacob, K. S., John, J. K., Verghese, A., & John, T. J. (1989). The Fear of AIDS: Psychiatric symptom or syndrome? *AIDS Care*, *1*(1), 35–38. https://doi.org/10.1080/09540128908260232

Jacob, R. G., Lilienfeld, S. O., Furman, J. M. R., Durrant, J. D., & Turner, S. M. (1989). Panic disorder with vestibular dysfunction: Further clinical observations and description

of space and motion phobic stimuli. *Journal of Anxiety Disorders*, *3*(2), 117–130. https://doi.org/10.1016/0887-6185(89)90006-6

Jaspal, R., Lopes, B., Bayley, J., & Papaloukas, P. (2019). A structural equation model to predict pre-exposure prophylaxis acceptability in men who have sex with men in Leicester, UK. *HIV Medicine*, *20*(1), 11–18. https://doi.org/10.1111/hiv.12667

Jaspal, R., & Bayley, J. (2020). Understanding the Clinical and Social Psychological Aspects of HIV. In *HIV and Gay Men*. Springer Singapore. https://doi.org/10.1007/978-981-15-7226-5_1

Jaspal, R., & Nerlich, B. (2016). A 'morning-after' pill for HIV? Social representations of post-exposure prophylaxis for HIV in the British print media. *Health, Risk and Society*, *18*(5–6), 225–246. https://doi.org/10.1080/13698575.2016.1222354

Jenness, S. M., Weiss, K. M., Goodreau, S. M., Gift, T., Chesson, H., Hoover, K. W., Smith, D. K., Liu, A. Y., Sullivan, P. S., & Rosenberg, E. S. (2017). Incidence of gonorrhea and chlamydia following human immunodeficiency virus preexposure prophylaxis among men who have sex with men: A modeling study. *Clinical Infectious Diseases*, *65*(5), 712–718. https://doi.org/10.1093/cid/cix439

Joffe, H. (2011). Thematic Analysis. In *Qualitative Research Methods in Mental Health and Psychotherapy: A Guide for Students and Practitioners* (pp. 209–223). John Wiley and Sons. https://doi.org/10.1002/9781119973249.ch15

Jootun, D., McGhee, G., & Marland, G. R. (2009). Reflexivity: promoting rigour in qualitative research. *Nursing Standard*, *23*(23), 42–47. https://go.gale.com/ps/i.do?p=HRCA&sw=w&issn=00296570&v=2.1&it=r&id=GALE%7CA194810332&sid=googleScholar&linkaccess=fulltext

Kasting, M. L., Shapiro, G. K., Rosberger, Z., Kahn, J. A., & Zimet, G. D. (2016). Tempest in a teapot: A systematic review of HPV vaccination and risk compensation research.

Human Vaccines and Immunotherapeutics, *12*(6), 1435–1450. https://doi.org/10.1080/21645515.2016.1141158

King, M. B. (1993). AIDS, HIV, and mental health. In *Cambridge University Press*. Cambridge University Press.

Klassen, B. J., Fulcher, K., Chown, S. A., Armstrong, H. L., Hogg, R. S., Moore, D. M., Roth, E. A., & Lachowsky, N. J. (2019). "condoms are ⋯ like public transit. It's something you want everyone else to take": Perceptions and use of condoms among HIV negative gay men in Vancouver, Canada in the era of biomedical and seroadaptive prevention. *BMC Public Health*, *19*(1), 1–13. https://doi.org/10.1186/s12889-019-6452-7

Klatzmann, D., Champagne, E., Chamaret, S., Gruest, J., Guetard, D., Hercend, T., Gluckman, J. C., & Montagnier, L. (1984). T-lymphocyte T4 molecule behaves as the receptor for human retrovirus LAV. *Nature*, *312*(5996), 767–768. https://doi.org/10.1038/312767a0

Koester, K., Amico, R. K., Gilmore, H., Liu, A., McMahan, V., Mayer, K., Hosek, S., & Grant, R. (2017). Risk, safety and sex among male PrEP users: time for a new understanding. *Culture, Health and Sexuality*, *19*(12), 1301–1313. https://doi.org/10.1080/13691058.2017.1310927

Krauss, S. (2015). Research Paradigms and Meaning Making: A Primer. *The Qualitative Report*, *10*(4), 758–770. https://doi.org/10.46743/2160-3715/2005.1831

Kvale, S. (1996). An Introduction to Qualitative Research Interviewing. In *The American Journal of Evaluation* (Issue 2). Sage. https://doi.org/10.1016/s1098-2140(99)80208-2

Lambert, C., Jomeen, J., & McSherry, W. (2010). Reflexivity: A review of the literature in the context of midwifery research. *British Journal of Midwifery*, *18*(5), 321–326. https://doi.org/10.12968/bjom.2010.18.5.47872

Landolt, M. A., Bartholomew, K., Saffrey, C., Oram, D., & Perlman, D. (2004). Gender nonconformity, childhood rejection, and adult attachment: A study of gay men. In *Archives of Sexual Behavior* (Vol. 33, Issue 2, pp. 117–128). Springer. https://doi.org/10.1023/B:ASEB.0000014326.64934.50

Larossa, R., Bennett, L. A., & Gelles, R. J. (1981). Ethical Dilemmas in Qualitative Family Research. *Journal of Marriage and the Family*, *43*(2), 303. https://doi.org/10.2307/351382

Latimer, R. L., Vodstrcil, L. A., Fairley, C. K., Cornelisse, V. J., Chow, E. P. F., Read, T. R. H., & Bradshaw, C. S. (2018). Non-consensual condom removal, reported by patients at a sexual health clinic in Melbourne, Australia. *PLoS ONE*, *13*(12), e0209779. https://doi.org/10.1371/journal.pone.0209779

Lerner, A. M., Eisinger, R. W., & Fauci, A. S. (2020). Comorbidities in Persons with HIV: The Lingering Challenge. In *JAMA - Journal of the American Medical Association* (Vol. 323, Issue 1, pp. 19–20). American Medical Association. https://doi.org/10.1001/jama.2019.19775

Lewis-Beck, M., Bryman, A., & Futing Liao, T. (2012). The SAGE Encyclopedia of Social Science Research Methods. In *The SAGE Encyclopedia of Social Science Research Methods*. Sage Publications, Inc. https://doi.org/10.4135/9781412950589

Leynaert, B., Downs, A. M., & De Vincenzi, I. (1998). Heterosexual transmission of human immunodeficiency virus: Variability of infectivity throughout the course of infection. *American Journal of Epidemiology*, *148*(1), 88–96. https://doi.org/10.1093/oxfordjournals.aje.a009564

Li, J., Gilmour, S., Zhang, H., Koyanagi, A., & Shibuya, K. (2012). The epidemiological impact and cost-effectiveness of HIV testing, antiretroviral treatment and harm

reduction programs. *AIDS*, *26*(16), 2069–2078. https://doi.org/10.1097/QAD.0b013e3283574e54

Lietz, C. A., Langer, C. L., & Furman, R. (2006). Establishing Trustworthiness in Qualitative Research in Social Work: Implications from a Study Regarding Spirituality. *Qualitative Social Work*, *5*(4), 441–458. https://doi.org/10.1177/1473325006070288

Lima, V. D., Geller, J., Bangsberg, D. R., Patterson, T. L., Daniel, M., Kerr, T., Montaner, J. S. G., & Hogg, R. S. (2007). The effect of adherence on the association between depressive symptoms and mortality among HIV-infected individuals first initiating HAART. *AIDS*, *21*(9), 1175–1183. https://doi.org/10.1097/QAD.0b013e32811ebf57

Link, B. G. (1987). Understanding Labeling Effects in the Area of Mental Disorders: An Assessment of the Effects of Expectations of Rejection. *American Sociological Review*, *52*(1), 96. https://doi.org/10.2307/2095395

Liu, A. Y., Cohen, S. E., Vittinghoff, E., Anderson, P. L., Doblecki-Lewis, S., Bacon, O., Chege, W., Postle, B. S., Matheson, T., Rivet Amico, K., Liegler, T., Keith Rawlings, M., Trainor, N., Blue, R. W., Estrada, Y., Coleman, M. E., Cardenas, G., Feaster, D. J., Grant, R., … Kolber, M. A. (2016). Preexposure prophylaxis for HIV infection integrated with municipal-and community-based sexual health services. *JAMA Internal Medicine*, *176*(1), 75–84. https://doi.org/10.1001/jamainternmed.2015.4683

Loewenberg, S. (2008). Selma Dritz. *The Lancet*, *372*(9646), 1296. https://doi.org/10.1016/s0140-6736(08)61539-1

Lorenc, T., Marrero-Guillamón, I., Llewellyn, A., Aggleton, P., Cooper, C., Lehmann, A., & Lindsay, C. (2011). HIV testing among men who have sex with men (MSM): Systematic review of qualitative evidence. In *Health Education Research* (Vol. 26, Issue 5, pp. 834–846). Health Educ Res. https://doi.org/10.1093/her/cyr064

Maas, M. K., & Lefkowitz, E. S. (2015). Sexual Esteem in Emerging Adulthood: Associations with Sexual Behavior, Contraception Use, and Romantic Relationships. *Journal of Sex Research*, *52*(7), 795–806. https://doi.org/10.1080/00224499.2014.945112

Marcus, D. K., Gurley, J. R., Marchi, M. M., & Bauer, C. (2007). Cognitive and perceptual variables in hypochondriasis and health anxiety: A systematic review. *Clinical Psychology Review*, *27*(2), 127–139. https://doi.org/10.1016/j.cpr.2006.09.003

Marcus, J. L., Leyden, W. A., Alexeeff, S. E., Anderson, A. N., Hechter, R. C., Hu, H., Lam, J. O., Towner, W. J., Yuan, Q., Horberg, M. A., & Silverberg, M. J. (2020). Comparison of Overall and Comorbidity-Free Life Expectancy Between Insured Adults With and Without HIV Infection, 2000-2016. *JAMA Network Open*, *3*(6), e207954. https://doi.org/10.1001/jamanetworkopen.2020.7954

Mastro, T. D., & de Vincenzi, I. (1996). Probabilities of sexual HIV-1 transmission. In *AIDS (London, England): Vol. 10 Suppl A*. AIDS. https://doi.org/10.1097/00002030-199601001-00011

Mayer, K. H., Agwu, A., & Malebranche, D. (2020). Barriers to the Wider Use of Pre-exposure Prophylaxis in the United States: A Narrative Review. In *Advances in Therapy* (Vol. 37, Issue 5, pp. 1778–1811). Adis. https://doi.org/10.1007/s12325-020-01295-0

McCormack, S., Dunn, D. T., Desai, M., Dolling, D. I., Gafos, M., Gilson, R., Sullivan, A. K., Clarke, A., Reeves, I., Schembri, G., Mackie, N., Bowman, C., Lacey, C. J., Apea, V., Brady, M., Fox, J., Taylor, S., Antonucci, S., Khoo, S. H., … Gill, O. N. (2016). Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): Effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *The Lancet*, *387*(10013), 53–60. https://doi.org/10.1016/S0140-6736(15)00056-2

McKay, R. A. (2014). “Patient Zero”: The absence of a patient’s view of the early North American AIDS epidemic. *Bulletin of the History of Medicine*, *88*(1), 161–194. https://doi.org/10.1353/bhm.2014.0005

McKusick, L., Horstman, W., & Coates, T. J. (1985). AIDS and sexual behavior reported by gay men in San Francisco. *American Journal of Public Health*, *75*(5), 493–496. https://doi.org/10.2105/AJPH.75.5.493

Mercer, C. H., Prah, P., Field, N., Tanton, C., MacDowall, W., Clifton, S., Hughes, G., Nardone, A., Wellings, K., Johnson, A. M., & Sonnenberg, P. (2016). The health and well-being of men who have sex with men (MSM) in Britain: Evidence from the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3). In *BMC Public Health* (Vol. 16, Issue 1, pp. 1–16). BioMed Central. https://doi.org/10.1186/s12889-016-3149-z

Merson, M. H., O’Malley, J., Serwadda, D., & Apisuk, C. (2008). The history and challenge of HIV prevention. In *The Lancet* (Vol. 372, Issue 9637, pp. 475–488). Elsevier B.V. https://doi.org/10.1016/S0140-6736(08)60884-3

Meyer, I. H. (1995). Minority stress and mental health in gay men. *Journal of Health and Social Behavior*, *36*(1), 38–56. https://doi.org/10.2307/2137286

Meyer, I. H. (2003). Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence. In *Psychological Bulletin* (Vol. 129, Issue 5, pp. 674–697). NIH Public Access. https://doi.org/10.1037/0033-2909.129.5.674

Milam, J., Jain, S., Dubé, M. P., Daar, E. S., Sun, X., Corado, K., Ellorin, E., Blumenthal, J., Haubrich, R., Moore, D. J., & Morris, S. R. (2019). Sexual Risk Compensation in a Pre-exposure Prophylaxis Demonstration Study among Individuals at Risk of HIV. *Journal*

of Acquired Immune Deficiency Syndromes, *80*(1), E9–E13. https://doi.org/10.1097/QAI.0000000000001885

Miller, D., Green, J., Farmer, R., & Carroll, G. (1985). A "Pseudo-AIDS" syndrome following from fear of AIDS. *British Journal of Psychiatry*, *146*(MAY), 550–551. https://doi.org/10.1192/bjp.146.5.550

Molina, J. M., Charreau, I., Spire, B., Cotte, L., Chas, J., Capitant, C., Tremblay, C., Rojas-Castro, D., Cua, E., Pasquet, A., Bernaud, C., Pintado, C., Delaugerre, C., Sagaon-Teyssier, L., Mestre, S. Le, Chidiac, C., Pialoux, G., Ponscarme, D., Fonsart, J., … Rabian, C. (2017). Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. *The Lancet HIV*, *4*(9), e402–e410. https://doi.org/10.1016/S2352-3018(17)30089-9

Molina, J.-M., Capitant, C., Spire, B., Pialoux, G., Cotte, L., Charreau, I., Tremblay, C., Le Gall, J.-M., Cua, E., Pasquet, A., Raffi, F., Pintado, C., Chidiac, C., Chas, J., Charbonneau, P., Delaugerre, C., Suzan-Monti, M., Loze, B., Fonsart, J., … Delfraissy, J.-F. (2015). On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. *New England Journal of Medicine*, *373*(23), 2237–2246. https://doi.org/10.1056/nejmoa1506273

Mowrer, O. H. (2009). Two-Factor Learning Theory: Versions One and Two. In *Learning theory and behavior.* (pp. 63–91). John Wiley & Sons Inc. https://doi.org/10.1037/10802-003

Mutua, G., Sanders, E., Mugo, P., Anzala, O., Haberer, J. E., Bangsberg, D., Barin, B., Rooney, J. F., Mark, D., Chetty, P., Fast, P., & Priddy, F. H. (2012). Safety and adherence to intermittent pre-exposure prophylaxis (PrEP) for HIV-1 in African men

who have sex with men and female sex workers. *PloS One*, *7*(4). https://doi.org/10.1371/journal.pone.0033103

Newcomb, M. E., & Mustanski, B. (2010). Internalized homophobia and internalizing mental health problems: A meta-analytic review. In *Clinical Psychology Review* (Vol. 30, Issue 8, pp. 1019–1029). Clin Psychol Rev. https://doi.org/10.1016/j.cpr.2010.07.003

NHS Scotland. (2020). *An Official Statistics publication for Scotland Implementation of HIV Pre-Exposure Prophylaxis (PrEP) in Scotland*. https://www.statisticsauthority.gov.uk/osr/code-of-practice/

Nicoll, A., & Gill, O. (1999). The global impact of HIV infection and disease. *Communicable Disease and Public Health*, *2*(2), 85–95.

Nicolosi, A., Leite, M. L. C., Musicco, M., Arid, C., Gavazzeni, G., Lazzarin, A., Angarano, G., Arici, C., Costigliola, P., Gafa, S., Gasparini, M., Gervasoni, C., Luzzati, R., Magnani, G., Moroni, M., Pristerà, R., Puppo, F., Salassa, B., Saracco, A., … Zerboni, R. (1994). The efficiency of male-to-female and female-to-male sexual transmission of the human immunodeficiency virus: A study of 730 stable couples. *Epidemiology*, *5*(6), 570–575. https://doi.org/10.1097/00001648-199411000-00003

Nungesser, L. (1983). *Homosexual Acts, Actors, and Identities: Amazon.co.uk: Nungesser, Lon G: 9780275910525: Books*. Praeger. https://www.amazon.co.uk/Homosexual-Acts-Actors-Identities-Nungesser/dp/0275910520

Nwokolo, N., Whitlock, G., & McOwan, A. (2017). Not just PrEP: other reasons for London's HIV decline. In *The Lancet HIV* (Vol. 4, Issue 4, p. e153). Elsevier Ltd. https://doi.org/10.1016/S2352-3018(17)30044-9

O'leary, D. (2014). The syndemic of AIDS and STDS among MSM. In *Linacre Quarterly* (Vol. 81, Issue 1, pp. 12–37). SAGE PublicationsSage CA: Los Angeles, CA. https://doi.org/10.1179/2050854913Y.0000000015

Okie, S. (2006). Fighting HIV — Lessons from Brazil. *New England Journal of Medicine*, *354*(19), 1977–1981. https://doi.org/10.1056/nejmp068069

Pachankis, J. E., & Goldfried, M. R. (2006). Social anxiety in young gay men. *Journal of Anxiety Disorders*, *20*(8), 996–1015. https://doi.org/10.1016/j.janxdis.2006.01.001

Pachankis, J. E., Goldfried, M. R., & Ramrattan, M. E. (2008). Extension of the Rejection Sensitivity Construct to the Interpersonal Functioning of Gay Men. *Journal of Consulting and Clinical Psychology*, *76*(2), 306–317. https://doi.org/10.1037/0022-006X.76.2.306

Palaganas, E. C., Sanchez, M. C., Molintas, M. V. P., & Caricativo, R. D. (2017). Reflexivity in qualitative research: A journey of learning. *Qualitative Report*, *22*(2), 426–438. https://doi.org/10.46743/2160-3715/2017.2552

Palella, F. J., Delaney, K. M., Moorman, A. C., Loveless, M. O., Fuhrer, J., Satten, G. A., Aschman, D. J., & Holmberg, S. D. (1998). Declining Morbidity and Mortality among Patients with Advanced Human Immunodeficiency Virus Infection. *New England Journal of Medicine*, *338*(13), 853–860. https://doi.org/10.1056/nejm199803263381301

Paparini, S., Nutland, W., Rhodes, T., Nguyen, V. K., & Anderson, J. (2018). DIY HIV prevention: Formative qualitative research with men who have sex with men who source PrEP outside of clinical trials. *PLoS ONE*, *13*(8), e0202830. https://doi.org/10.1371/journal.pone.0202830

Parahoo, K. (2006). *Nursing Research: Principles, Process and Issues* (2nd ed.). Palgrave Macmillan. https://pure.ulster.ac.uk/en/publications/nursing-research-principles-process-and-issues-second-edition-3

Parikh, U. M., & Mellors, J. W. (2016). Should we fear resistance from tenofovir/emtricitabine preexposure prophylaxis? In *Current Opinion in HIV and AIDS*

(Vol. 11, Issue 1, pp. 49–55). Lippincott Williams and Wilkins. https://doi.org/10.1097/COH.0000000000000209

Parrish, C. L., Radomsky, A. S., & Dugas, M. J. (2008). Anxiety-control strategies: Is there room for neutralization in successful exposure treatment? In *Clinical Psychology Review* (Vol. 28, Issue 8, pp. 1400–1412). Clin Psychol Rev. https://doi.org/10.1016/j.cpr.2008.07.007

Patton, M. (2015). *Qualitative Research & Evaluation Methods* . Sage Publications Inc. https://us.sagepub.com/en-us/nam/qualitative-research-evaluation-methods/book232962

Phillips, A. N., Bansi-Matharu, L., Cambiano, V., Ehrenkranz, P., Serenata, C., Venter, F., Pett, S., Flexner, C., Jahn, A., Revill, P., & Garnett, G. P. (2021). The potential role of long-acting injectable cabotegravir–rilpivirine in the treatment of HIV in sub-Saharan Africa: a modelling analysis. *The Lancet Global Health*, *9*(5), e620–e627. https://doi.org/10.1016/s2214-109x(21)00025-5

Piot, P., Bartos, M., Larson, H., Zewdie, D., & Mane, P. (2008). Coming to terms with complexity: a call to action for HIV prevention. In *The Lancet* (Vol. 372, Issue 9641, pp. 845–859). Elsevier B.V. https://doi.org/10.1016/S0140-6736(08)60888-0

Potrata, B. (2010). Rethinking the Ethical Boundaries of a Grounded Theory Approach. *Research Ethics*, *6*(4), 154–158. https://doi.org/10.1177/174701611000600408

Prestage, G., Brown, G., & Keen, P. (2012). Barriers to HIV testing among Australian gay men. In *Sexual Health* (Vol. 9, Issue 5, pp. 453–458). CSIRO PUBLISHING. https://doi.org/10.1071/SH12033

Public Health England. (2020). *HIV in the United Kingdom* . https://www.gov.uk/government/publications/hiv-in-the-united-kingdom

Rachman, S. (1977). The conditioning theory of fearacquisition: A critical examination. *Behaviour Research and Therapy*, *15*(5), 375–387. https://doi.org/10.1016/0005-7967(77)90041-9

Rachman, S. (2003). *The Treatment of Obsessions*. Oxford University Press. https://global.oup.com/academic/product/the-treatment-of-obsessions-9780198515371?cc=gb&lang=en&

Rachman, S., & Hodgson, R. (1980). *Obsessions and compulsions* . Prentice Hall. https://www.semanticscholar.org/paper/Obsessions-and-compulsions-%3A-S.J.-Rachman-and-R.J.-Foa/599f08e0c16c2b924ea4969572a621d7d82b9d3e

Rasmussen, L. M., & Richey, L. A. (2012). The Lazarus Effect of AIDS Treatment: Lessons Learned and Lives Saved. *Journal of Progressive Human Services*, *23*(3), 187–207. https://doi.org/10.1080/10428232.2012.717249

Ritchie, J., Lewis, J., Nicholls, C., & Ormston, R. (2014). Qualitative Research Practice: A Guide for Social Science Students and Researchers. In *undefined*. Sage.

Rodger, A. J., Cambiano, V., Bruun, T., Vernazza, P., Collins, S., Van Lunzen, J., Corbelli, G. M., Estrada, V., Geretti, A. M., Beloukas, A., Asboe, D., Viciana, P., Gutiérrez, F., Clotet, B., Pradier, C., Gerstoft, J., Weber, R., Westling, K., Wandeler, G., … Lundgren, J. (2016). Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. *JAMA - Journal of the American Medical Association*, *316*(2), 171–181. https://doi.org/10.1001/jama.2016.5148

Rodger, A. J., Cambiano, V., Phillips, A. N., Bruun, T., Raben, D., Lundgren, J., Vernazza, P., Collins, S., Degen, O., Corbelli, G. M., Estrada, V., Geretti, A. M., Beloukas, A., Beloukas, A., Coll, P., Antinori, A., Nwokolo, N., Rieger, A., Prins, J. M., … Janeiro, N. (2019). Risk of HIV transmission through condomless sex in serodifferent gay

couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. *The Lancet*, *393*(10189), 2428–2438. https://doi.org/10.1016/S0140-6736(19)30418-0

Rotello, G. (1997). *Sexual Ecology: AIDS and the Destiny of Gay Men*. E P Dutton. https://www.amazon.co.uk/Sexual-Ecology-AIDS-Destiny-Gay/dp/0525941649

Rouf, K. (2016). Oxford Guide to Behavioural Experiments in Cognitive Therapy. In *Oxford Guide to Behavioural Experiments in Cognitive Therapy*. Oxford University Press. https://doi.org/10.1093/med:psych/9780198529163.001.0001

Roulston, K. (2001). Data analysis and 'theorizing as ideology.' *Qualitative Research*, *1*(3), 279–302. https://doi.org/10.1177/146879410100100302

Sabin, C. A., & Lundgren, J. D. (2013). The natural history of HIV infection. *Current Opinion in HIV and AIDS*, *8*(4), 311–317. https://doi.org/10.1097/COH.0b013e328361fa66

Safren, S. A., & Heimberg, R. G. (1999). Depression, hopelessness, suicidality, and related factors in sexual minority and heterosexual adolescents. *Journal of Consulting and Clinical Psychology*, *67*(6), 859–866. https://doi.org/10.1037//0022-006x.67.6.859

Sagaon-Teyssier, L., Suzan-Monti, M., Demoulin, B., Capitant, C., Lorente, N., Préau, M., Mora, M., Rojas Castro, D., Chidiac, C., Chas, J., Meyer, L., Molina, J. M., & Spire, B. (2016). Uptake of PrEP and condom and sexual risk behavior among MSM during the ANRS IPERGAY trial. *AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV*, *28*(sup1), 48–55. https://doi.org/10.1080/09540121.2016.1146653

Salkoviskis, P., & Bass, C. (1997). Hypochondriasis. In D. Clark & C. Fairburn (Eds.), *Science and practice of cognitive behaviour therapy* (pp. 313–339). Oxford University Press. https://psycnet.apa.org/record/1997-97380-013

Salkovskis, P. M., Forrester, E., & Richards, C. (1998). Cognitive-behavioural approach to understanding obsessional thinking. In *British Journal of Psychiatry* (Vol. 173, Issue SUPPL. 35, pp. 53–63). Royal College of Psychiatrists. https://doi.org/10.1192/s0007125000297900

Salkovskis, P. M., Rimes, K. A., Warwick, H. M. C., & Clark, D. M. (2002). The health anxiety inventory: Development and validation of scales for the measurement of health anxiety and hypochondriasis. *Psychological Medicine*, *32*(5), 843–853. https://doi.org/10.1017/S0033291702005822

Salkovskis, P. M. (1991). The Importance of Behaviour in the Maintenance of Anxiety and Panic: A Cognitive Account. *Behavioural Psychotherapy*, *19*(1), 6–19. https://doi.org/10.1017/S0141347300011472

Salkovskis, P. M., Clark, D. M., & Gelder, M. G. (1996). Cognition-behaviour links in the persistence of panic. *Behaviour Research and Therapy*, *34*(5–6), 453–458. https://doi.org/10.1016/0005-7967(95)00083-6

Sandfort, T. G. M., De Graaf, R., Bijl, R. V., & Schnabel, P. (2001). Same-sex sexual behavior and psychiatric disorders: Findings from the Netherlands mental health survey and incidence study (NEMESIS). *Archives of General Psychiatry*, *58*(1), 85–91. https://doi.org/10.1001/archpsyc.58.1.85

Sandström, E. G., & Kaplan, J. C. (1987). Antiviral Therapy in AIDS: Clinical Pharmacological Properties and Therapeutic Experience to Date. In *Drugs* (Vol. 34, Issue 3, pp. 372–390). Springer. https://doi.org/10.2165/00003495-198734030-00004

Sax, P. E., Tierney, C., Collier, A. C., Fischl, M. A., Mollan, K., Peeples, L., Godfrey, C., Jahed, N. C., Myers, L., Katzenstein, D., Farajallah, A., Rooney, J. F., Ha, B., Woodward, W. C., Koletar, S. L., Johnson, V. A., Geiseler, P. J., & Daar, E. S. (2009). Abacavir–Lamivudine versus Tenofovir–Emtricitabine for Initial HIV-1 Therapy. *New*

England Journal of Medicine, *361*(23), 2230–2240. https://doi.org/10.1056/nejmoa0906768

Scholten, M., Suárez, I., Platten, M., Kümmerle, T., Jung, N., Wyen, C., Ernst, A., Horn, C., Burst, V., Suárez, V., Rybniker, J., Fätkenheuer, G., & Lehmann, C. (2018). To prescribe, or not to prescribe: decision making in HIV-1 post-exposure prophylaxis. *HIV Medicine*, *19*(9), 645–653. https://doi.org/10.1111/hiv.12645

Scragg, P. (1995). A critical analysis of morbid fear of HIV/AIDS. *Clinical Psychology & Psychotherapy*, *2*(4), 278–284. https://doi.org/10.1002/cpp.5640020410

Selik, R. M., Chu, S. Y., & Ward, J. W. (1995). Trends in infectious diseases and cancers among persons dying of HIV infection in the United States from 1987 to 1992. *Annals of Internal Medicine*, *123*(12), 933–936. https://doi.org/10.7326/0003-4819-123-12-199512150-00006

Shaffir, W., & Stebbins, R. (2014). Experiencing Fieldwork: An Inside View of Qualitative Research. In *Experiencing Fieldwork: An Inside View of Qualitative Research*. SAGE Publications, Inc. https://doi.org/10.4135/9781483325514

Sharma, E., & Math, S. (2019). Course and outcome of obsessive-compulsive disorder. In *Indian Journal of Psychiatry* (Vol. 61, Issue 7, pp. S43–S50). Wolters Kluwer Medknow Publications. https://doi.org/10.4103/psychiatry.IndianJPsychiatry_521_18

Shaw, G. M., & Hunter, E. (2012). HIV transmission. *Cold Spring Harbor Perspectives in Medicine*, *2*(11). https://doi.org/10.1101/cshperspect.a006965

Shear, M. K., Bjelland, I., Beesdo, K., Gloster, A. T., & Wittchen, H.-U. (2007). Supplementary dimensional assessment in anxiety disorders. *International Journal of Methods in Psychiatric Research Int. J. Methods Psychiatr. Res*, *16*(S1), 52–64. https://doi.org/10.1002/mpr.215

Shenton, A. K. (2004). Strategies for ensuring trustworthiness in qualitative research projects. *Education for Information*, *22*(2), 63–75. https://doi.org/10.3233/EFI-2004-22201

Shernoff, M. (2006). *Without condoms: Unprotected sex, gay men and barebacking.* . Routledge. https://psycnet.apa.org/record/2006-01384-000

Silverman, D. (2013). *Doing Qualitative Research A Practical Handbook* (4th ed.). Sage. http://research.gold.ac.uk/id/eprint/13622/

Skidmore, W. C., Linsenmeier, J. A. W., & Bailey, J. M. (2006). Gender nonconformity and psychological distress in lesbians and gay men. *Archives of Sexual Behavior*, *35*(6), 685–697. https://doi.org/10.1007/s10508-006-9108-5

Smith, D. K., Herbst, J. H., Zhang, X., & Rose, C. E. (2015). Condom effectiveness for HIV prevention by consistency of use among men who have sex with men in the United States. *Journal of Acquired Immune Deficiency Syndromes*, *68*(3), 337–344. https://doi.org/10.1097/QAI.0000000000000461

Smith, J. A. (1996). Beyond the divide between cognition and discourse: using interpretative phenomenological analysis in health psychology. *Psychology and Health*, *11*(2), 261–271. https://doi.org/10.1080/08870449608400256

Smith, J., Flowers, P., & Larkin, M. (2009). *Interpretative Phenomenological Analysis: Theory, Method and Research*. Sage. https://books.google.co.uk/books/about/Interpretative_Phenomenological_Analysis.html?id=WZ2Dqb42exQC

Snowden, J. M., Chen, Y. H., McFarland, W., & Raymond, H. F. (2017). Prevalence and characteristics of users of pre-exposure prophylaxis (PrEP) among men who have sex with men, San Francisco, 2014 in a cross-sectional survey: Implications for disparities. *Sexually Transmitted Infections*, *93*(1), 52–55. https://doi.org/10.1136/sextrans-2015-052382

St. Clair, M. H., Richards, C. A., Spector, T., Weinhold, K. J., Miller, W. H., Langlois, A. J., & Furman, P. A. (1987). 3'-Azido-3'-deoxythymidine triphosphate as an inhibitor and substrate of purified human immunodeficiency virus reverse transcriptase. *Antimicrobial Agents and Chemotherapy*, *31*(12), 1972–1977. https://doi.org/10.1128/AAC.31.12.1972

Starks, H., & Trinidad, S. B. (2007). Choose your method: A comparison of phenomenology, discourse analysis, and grounded theory. *Qualitative Health Research*, *17*(10), 1372–1380. https://doi.org/10.1177/1049732307307031

Storholm, E. D., Volk, J. E., Marcus, J. L., Silverberg, M. J., & Satre, D. D. (2017). Risk Perception, Sexual Behaviors, and PrEP Adherence Among Substance-Using Men Who Have Sex with Men: a Qualitative Study. *Prevention Science*, *18*(6), 737–747. https://doi.org/10.1007/s11121-017-0799-8

Sylva, D., Rieger, G., Linsenmeier, J. A. W., & Bailey, J. M. (2010). Concealment of sexual orientation. *Archives of Sexual Behavior*, *39*(1), 141–152. https://doi.org/10.1007/s10508-008-9466-2

Tan, D. H. S., Hull, M. W., Yoong, D., Tremblay, C., O'Byrne, P., Thomas, R., Kille, J., Baril, J. G., Cox, J., Giguere, P., Harris, M., Hughes, C., MacPherson, P., O'Donnell, S., Reimer, J., Singh, A., Barrett, L., Bogoch, I., Jollimore, J., … Shafran, S. (2017). Canadian guideline on HIV pre-exposure prophylaxis and nonoccupational postexposure prophylaxis. *CMAJ*, *189*(47), E1448–E1458. https://doi.org/10.1503/cmaj.170494

Thoits, P. A. (1985). Social Support and Psychological Well-Being: Theoretical Possibilities. In *Social Support: Theory, Research and Applications* (pp. 51–72). Springer Netherlands. https://doi.org/10.1007/978-94-009-5115-0_4

Thwaites, R., & Freeston, M. H. (2005). Safety-seeking behaviours: Fact or function? How can we clinically differentiate between safety behaviours and adaptive coping strategies

across anxiety disorders? In *Behavioural and Cognitive Psychotherapy* (Vol. 33, Issue 2, pp. 177–188). https://doi.org/10.1017/S1352465804001985

Traeger, M. W., Cornelisse, V. J., Asselin, J., Price, B., Roth, N. J., Willcox, J., Tee, B. K., Fairley, C. K., Chang, C. C., Armishaw, J., Vujovic, O., Penn, M., Cundill, P., Forgan-Smith, G., Gall, J., Pickett, C., Lal, L., Mak, A., Spelman, T. D., … Wright, E. J. (2019). Association of HIV Preexposure Prophylaxis With Incidence of Sexually Transmitted Infections Among Individuals at High Risk of HIV Infection. *JAMA*, *321*(14), 1380–1390. https://doi.org/10.1001/jama.2019.2947

Troiden, R. R. (1988). Homosexual identity development. *Journal of Adolescent Health Care*, *9*(2), 105–113. https://doi.org/10.1016/0197-0070(88)90056-3

Tsai, C. C., Follis, K. E., Sabo, A., Beck, T. W., Grant, R. F., Bischofberger, N., Benveniste, R. E., & Black, R. (1995). Prevention of SIV infection in macaques by (R)-9-(2-phosphonylmethoxypropyl)adenine. *Science*, *270*(5239), 1197–1199. https://doi.org/10.1126/science.270.5239.1197

Tumarkin, E., Siedner, M. J., & Bogoch, I. I. (2019). HIV pre-exposure prophylaxis (PrEP). *BMJ (Online)*, *364*. https://doi.org/10.1136/bmj.k4681

Vaccher, S. J., Gianacas, C., Templeton, D. J., Poynten, I. M., Haire, B. G., Ooi, C., Foster, R., McNulty, A., Grulich, A. E., & Zablotska, I. B. (2017). Baseline preferences for daily, event-driven, or periodic hiv pre-exposure prophylaxis among gay and bisexual men in the prelude demonstration project. *Frontiers in Public Health*, *5*. https://doi.org/10.3389/fpubh.2017.00341

Van Rompay, K. K. A., McChesney, M. B., Aguirre, N. L., Schmidt, K. A., Bischofberger, N., & Marthas, M. L. (2001). Two low doses of tenofovir protect newborn macaques against oral simian immunodeficiency virus infection. *Journal of Infectious Diseases*, *184*(4), 429–438. https://doi.org/10.1086/322781

Verdinelli, S., & Scagnoli, N. I. (2013). Data display in qualitative research. *International Journal of Qualitative Methods*, *12*(1), 359–381. https://doi.org/10.1177/160940691301200117

Vincke, J., Bolton, R., & De Vleeschouwer, P. (2001). The cognitive structure of the domain of safe and unsafe gay sexual behaviour in Belgium. *AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV*, *13*(1), 57–70. https://doi.org/10.1080/09540120020018189

Vosvick, M., Fritz, S., Henry, D., Prybutok, V., Sheu, S., & Poe, J. (2016). Correlates and Racial/Ethnic Differences in Bareback Sex Among Men Who Have Sex with Men with Unknown or Negative HIV Serostatus. *AIDS and Behavior*, *20*(12), 2798–2811. https://doi.org/10.1007/s10461-016-1366-1

Vosvick, M., Fritz, S., Henry, D., Prybutok, V., Sheu, S., & Poe, J. (2016). Correlates and Racial/Ethnic Differences in Bareback Sex Among Men Who Have Sex with Men with Unknown or Negative HIV Serostatus. *AIDS and Behavior*, *20*(12), 2798–2811. https://doi.org/10.1007/s10461-016-1366-1

Vuorio, K. A., Aarela, E., & Lehtinen, V. (1990). Eight cases of patients with unfounded fear of AIDS. *International Journal of Psychiatry in Medicine*, *20*(4), 405–411. https://doi.org/10.2190/GVPC-EXK6-LF35-PBCJ

Walensky, R. P., Paltiel, A. D., Losina, E., Mercincavage, L. M., Schackman, B. R., Sax, P. E., Weinstein, M. C., & Freedberg, K. A. (2006). The survival benefits of AIDS treatment in the United States. *Journal of Infectious Diseases*, *194*(1), 11–19. https://doi.org/10.1086/505147

Ward, R. L., Bernstein, D. I., Young, E. C., Sherwood, J. R., Knowlton, D. R., & Schiff, G. M. (1986). Human rotavirus studies in volunteers: Determination of infectious dose and

serological response to infection. *Journal of Infectious Diseases*, *154*(5), 871–880. https://doi.org/10.1093/infdis/154.5.871

Warwick, H. M. C., & Salkovskis, P. M. (1990). Hypochondriasis. *Behaviour Research and Therapy*, *28*(2), 105–117. https://doi.org/10.1016/0005-7967(90)90023-C

Watkins, E. S. (2001). *On the Pill: A Social History of Oral Contraceptives, 1950-1970* . John Hopkins University Press. https://books.google.co.uk/books/about/On_the_Pill.html?id=PXz7WtS1-LsC&source=kp_book_description&redir_esc=y

Weaver, M. A., Raymond, E. G., & Baecher, L. (2009). Attitude and behavior effects in a randomized trial of increased access to emergency contraception. *Obstetrics and Gynecology*, *113*(1), 107–116. https://doi.org/10.1097/AOG.0b013e318190c0fe

Westbrook, D., Kennerley, H., & Kirk, J. (2007). *An Introduction to Cognitive Behaviour Therapy: Skills and Application*. Sage.

Whitfield, T. H. F., Jones, S. S., Wachman, M., Grov, C., Parsons, J. T., & Rendina, H. J. (2019). The Impact of Pre-Exposure Prophylaxis (PrEP) Use on Sexual Anxiety, Satisfaction, and Esteem Among Gay and Bisexual Men. *Journal of Sex Research*, *56*(9), 1128–1135. https://doi.org/10.1080/00224499.2019.1572064

Wilde, G. J. S. (1998). Risk homeostasis theory: An overview. In *Injury Prevention* (Vol. 4, Issue 2, pp. 89–91). BMJ Publishing Group Ltd. https://doi.org/10.1136/ip.4.2.89

Wilkinson, S. (1999). Focus groups: A feminist method. *Psychology of Women Quarterly*, *23*(2), 221–244. https://doi.org/10.1111/j.1471-6402.1999.tb00355.x

Windgassen, E., & Soni, S. D. (1987). AIDS panic. In *The British journal of psychiatry : the journal of mental science* (Vol. 151, pp. 126–127). https://doi.org/10.1192/bjp.151.1.126

Witzel, T. C., Nutland, W., & Bourne, A. (2019). What are the motivations and barriers to pre-exposure prophylaxis (PrEP) use among black men who have sex with men aged 18-45 in London? Results from a qualitative study. *Sexually Transmitted Infections*, *95*(4), 262–266. https://doi.org/10.1136/sextrans-2018-053773

Wood, E., Montaner, J. S., & Kerr, T. (2008). Illicit drug addiction, infectious disease spread, and the need for an evidence-based response. In *The Lancet Infectious Diseases* (Vol. 8, Issue 3, pp. 142–143). Lancet Infect Dis. https://doi.org/10.1016/S1473-3099(08)70021-5

Woods, W. J., Euren, J., Pollack, L. M., & Binson, D. (2010). HIV prevention in gay bathhouses and sex clubs across the United States. In *Journal of Acquired Immune Deficiency Syndromes* (Vol. 55, Issue SUPPL. 2, p. S88). NIH Public Access. https://doi.org/10.1097/QAI.0b013e3181fbca1b

Worobey, M., Watts, T. D., McKay, R. A., Suchard, M. A., Granade, T., Teuwen, D. E., Koblin, B. A., Heneine, W., Lemey, P., & Jaffe, H. W. (2016). 1970s and "Patient 0" HIV-1 genomes illuminate early HIV/AIDS history in North America. *Nature*, *539*(7627), 98–101. https://doi.org/10.1038/nature19827

Yarchoan, R., Weinhold, K. J., Lyerly, H. K., Gelmann, E., Blum, R. M., Shearer, G. M., Mitsuya, H., Collins, J. M., Myers, C. E., Klecker, R. W., Markham, P. D., Durack, D. T., Lehrman, S. N., Barry, D. W., Fischl, M. A., Gallo, R. C., Bolognesi, D. P., & Broder, S. (1986). ADMINISTRATION OF 3'-AZIDO-3'-DEOXYTHYMIDINE, AN INHIBITOR OF HTLV-III/LAV REPLICATION, TO PATIENTS WITH AIDS OR AIDS-RELATED COMPLEX. *The Lancet*, *327*(8481), 575–580. https://doi.org/10.1016/S0140-6736(86)92808-4

Young, S. D., Nussbaum, A. D., & Monin, B. (2007). Potential moral stigma and reactions to sexually transmitted diseases: Evidence for a disjunction fallacy. *Personality and Social Psychology Bulletin*, *33*(6), 789–799. https://doi.org/10.1177/0146167207301027

Zimmermann, H. M. L., Eekman, S. W., Achterbergh, R. C. A., Schim van der Loeff, M. F., Prins, M., de Vries, H. J. C., Hoornenborg, E., & Davidovich, U. (2019). Motives for choosing, switching and stopping daily or event-driven pre-exposure prophylaxis – a qualitative analysis. *Journal of the International AIDS Society*, *22*(10). https://doi.org/10.1002/jia2.25389

APPENDICIES

Appendix A

Participant Information Sheet (PIS)

Participant Information Sheet

A study exploring the experiences of low risk men who have sex with men who are using HIV pre-exposure prophylaxis (PrEP)

We invite you to take part in a research study

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it friends, relatives and your sexual health clinician if you wish.
- You are free to decide whether or not to take part in the study. If you choose not to take part, this will not affect the care you are receiving from your sexual health clinic.
- Ask us if there is anything that is not clear or if you would like more information.

Important things that you need to know

- We want to find out what the experiences are of men who have sex with men who are taking HIV pre-exposure prophylaxis (PrEP).
- If you choose to participate then you will be asked to complete a questionnaire and take part in a one-to-one interview with a trained researcher.
- It is unlikely that the study will evoke any significant psychological distress.
- This study can fit into your normal clinic appointments, so there will be no extra visits, unless you wish to be interviewed at a more suitable time. There is also an option to interview remotely (using secure computer software).
- You can stop taking part in the study at any time.

Who is conducting this study?
This research is being carried out by Mr Christopher McCormack who is a Trainee Clinical Psychologist from the University of Essex and Essex Partnership University NHS Foundation Trust. The research is being supervised by Professor Gill Green from the School of Health &

[redacted]

What is the purpose of the study?
The purpose of this study is to try and better understand the experiences of men who are having sex with men who are using PrEP and are considered to be low risk (i.e. not having condomless anal sex). The study is being carried out as part of the requirements of the Doctorate in Clinical Psychology training course at the University of Essex. The study will involve talking to men who are using PrEP. All participants will be asked about their motivations for starting PrEP and to reflect on the impact taking PrEP has had on them. It is hoped that the interviews will provide us with a better understanding of the experiences of taking PrEP in this group. The study aims to recruit 20 participants.

Why have I been invited?
We are inviting men who have sex with men who are currently using PrEP and were considered to be low risk (i.e., not having condomless anal sex) of HIV infection, prior to starting PrEP. We believe you may fit these criteria and that is why we have invited you to take part.

What does participating involve?
If you decide to take part in the study, you will be asked to:

1. Let the clinician who told you about the study know that you are happy to learn more about the study and they will pass your details to Christopher McCormack who will contact you (via telephone or email).

2. Christopher will give you more information about the study, answer any questions you have and if you still would like to take part, he will arrange an appointment with you. This appointment will take place at your sexual health clinic or remotely using secure computer software.

3. Before you begin the interview, Christopher will ask you to sign a consent form to agree to take part in the study. If you are participating remotely, you will be emailed a link to complete the form using secure computer software.

4. Christopher will then ask you to complete an 18-item questionnaire that will ask you questions about anxiety.

5. Your interview will last around one hour and will be an informal discussion. Christopher will ask you some questions about what motivated you to start taking PrEP and about the impact it has had on various parts of your life.

You can take a break at any time during the interview, and you don't have to answer any questions that you don't want to. The interviews will be audio recorded to make sure that what is written down in the study matches exactly what each participant says. Some quotes from your interview may be included in the research paper, but you will not be identified from any of the information.

Do I have to take part?

No. Your decision to take part or not to take part is entirely up to you. If you agree to take part, you will be asked to sign a consent form before you start your interview, so that there is a record of your consent. You will also be given a copy of the signed consent form. However, if you do not wish to take part then this is absolutely fine; it will in no way impact the care you are receiving from your sexual health clinic.

Furthermore, should you initially agree to participate and then change your mind then this is also okay and would in no way impact the care you are receiving from your sexual health clinic. However, due to the nature of the study any data already anonymised will be retained following your withdrawal from the study. You can withdraw from the study by contacting someone in the study team (the specific contact details are included at the end of this information sheet).

What happens to the information?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The Data Controller is the University of Essex and the named person is Sara Stock (University Information Assurance Manager) who can be contacted by emailing dpo@essex.ac.uk.

We will be using information from you in order to undertake this study and will use the minimum personally identifiable information possible. We will keep identifiable information about you for 12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Essex for 5 years after the end of the study.

The audio recordings and any written information will be encrypted and kept under password on a locked computer. A professional transcriber (who has signed a confidentiality agreement) will transcribe the audio recordings. This information will then be transferred to a secure University of Essex network once the study has concluded. The data will be kept here for up to 12 months, after which time the information will be destroyed. The information will be stored in accordance with the Data Protection Act 2018, which means that we lock it securely and cannot reveal it to others without your prior permission.

Your name and personal information will be known to the researchers but will be saved [redacted]

team is conducting the study correctly.

A copy of the completed consent form will be archived in your sexual health records and stored in accordance with Trust policy for the retention of medical records.

The results of this study may be published in academic journals, conference proceedings and as a piece of work for a doctoral qualification in Clinical Psychology. Some direct quotes from your interview may be included in these reports/publications and whilst every effort will be made to anonymise quotes, anonymity cannot be guaranteed.

At the end of the study, a standard feedback letter will be offered to each participant summarising the study findings. This is not a requirement to participate in the study; participants will consent to 'opt-in' and provide an e-mail address for the Chief Investigator to send the standard feedback letter to. This e-mail address will be stored separately to the audio recordings and will only be used in the context of sending the standard feedback letter; they will not be linked to any other personal information.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://www1.essex.ac.uk/records_management/policies/data_protection_and_research.aspx You can find more about how we use your information by contacting anyone on the study team. Their contact details are included at the end of this information sheet.

What are the possible benefits of taking part?
Your participation will help develop an understanding of the experiences of PrEP-using men who have sex with men who are relatively low risk of acquiring HIV infection. It is hoped that you may find some benefit from having an opportunity to talk and reflect on your experiences.

At any point, if you feel distressed during or after the interview, we will ensure that you have information to access appropriate support, if you need to.

What are the possible risks of taking part?
There is the potential for the interview to elicit some psychological distress. The questions might also highlight that you may be experiencing anxiety related to HIV or your sexual health. The researcher will be able to help you with any distress that may occur as a result or in response to the interview, this may involve offering you a referral for further support. Based on your responses to the questions, the researcher may identify a possible anxiety disorder called Health Anxiety (which is also sometimes referred to as Illness Anxiety Disorder). You can read more about Health Anxiety at https://www.nhs.uk/conditions/health-anxiety/ . If this is the case, you will be offered an onward referral to a specialist for further assessment and possible psychological intervention. There are also risks associated with taking PrEP that you should be aware of. Your clinician at the clinic will have discussed these with you. However, if you want to find more information regarding the risks associated with PrEP use please see the NHS endorsed iBase PrEP information Leaflet (this can be found at http://i-base.info/guides/wp-content/uploads/2019/11/UK-guide-to-PrEP-Nov-2019-FINAL.pdf).

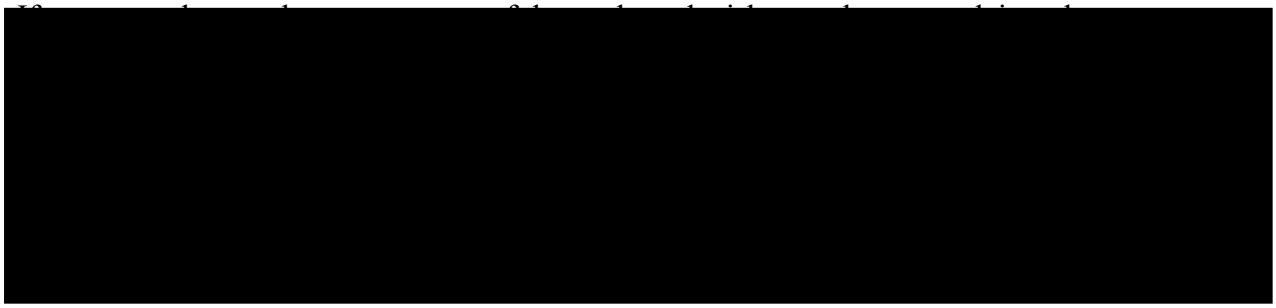
It is acknowledged that some participants will be acquiring their PrEP online. Whilst the main risk arises from taking PrEP without having any baseline tests, you should always discuss where you are sourcing PrEP with a health advisor, nurse or doctor at the clinic. They can advise you further regarding the safety risks associated with this, as NHS clinics are only responsible for the medication which they supply. It is important to adhere to any recommendations made by the clinicians at your clinic regarding ongoing monitoring whilst you are using PrEP, to ensure that you are taking PrEP as safely as you can.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by the London-Camberwell St Giles Research Ethics Committee.

What if you have a complaint about any aspect of the study?
If you have any concerns about any aspect of the study or have a complaint, in the first instance please contact the chief investigator of the project, Christopher McCormack, using the contact details below. If are still concerned, you think your complaint has not been addressed to your satisfaction or you feel that you cannot approach the chief investigator, please contact either their supervisor or the departmental Director of Research in the department responsible for this project, Dr Ewan Speed (esspeed@essex.ac.uk). If you are still not satisfied, please contact the University's Research Governance and Planning Manager, Sarah Manning-Press (e-mail sarahm@essex.ac.uk). University of Essex, Wivenhoe Park, Colchester, Essex, C04 3SQ.

How to make a complain to Patient Advice and Liaison Service (PALS)?



If you have any further questions?
We will give you a copy of the information sheet and signed consent form to keep. If you would like more information, the researcher contact details are below:

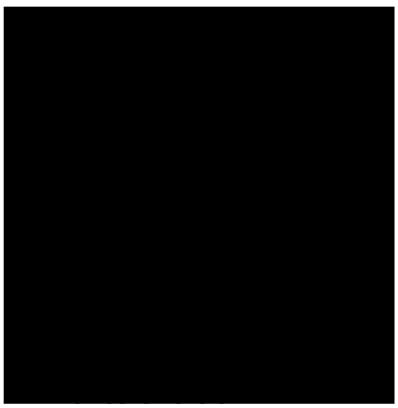
Researcher(s) Contact Details:

Professor Gill Green
School of Health & Social Care
University of Essex
Colchester
CO4 3SQ

Email:
gillgr@essex.ac.uk
Tel: 01206 874144

Mr Christopher McCormack
School of Health & Social Care
University of Essex
Colchester
CO4 3SQ

Email:
christopher.mccormack@nhs.net
Tel: 01206 874144



Appendix B

Consent Form

IRAS ID: 266963

Centre Number:

Study Number:

Participant Identification Number for this study:

CONSENT FORM

Title of Project: The experiences of non-high-risk men who have sex with men who are using HIV pre-exposure prophylaxis (PrEP)

Name of Researcher: Christopher McCormack

	Please initial box
1. I confirm that I have read the information sheet dated 27 April 2020 (version 2.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
3. I agree to be interviewed either in person or remotely (using Zoom).	☐
4. I agree to my interview being audio recorded.	☐
5. I agree to completing the questionnaire.	☐
6. I understand that the identifiable data provided will be securely stored and accessible	☐

only to the members of the research team directly involved in the project and a professional transcriber, and that confidentiality will be maintained.

7. I understand that my fully anonymised data will be used for publication in academic journals, conference proceedings and as a piece of work for a doctoral qualification in clinical psychology. ☐

8. I understand that anonymised quotes from the interviews will be included in the study write up. ☐

9. The results will be disseminated to those who participate in the form of letter summarising the findings. These will be sent via email. This is entirely optional: If you would like to receive the letter please initial the corresponding box; if you do not wish to receive the letter, please leave blank. ☐

10. I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers. ☐

11. I agree to take part in the above study. ☐

NOTE: 1 copy of this consent form will be retained by the researcher; 1 copy will be uploaded onto your clinic notes; and 1 copy will be provided to you, the participant.

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix C

Health Anxiety Inventory

SHORT MONTH

Ass / Wk / Sess: _____

HAI

Each question is this section consists of a group of four statements. Please read each group of statements carefully and then select the one which best describes your feelings, OVER THE PAST SIX MONTHS. Identify the statement by ringing the letter next to it ie. if you think that statement (a) is correct, ring statement (a); it may be that more than one statement applies, in which case, please ring any that are applicable.

1. a. I do not worry about my health.
   b. I occasionally worry about my health.
   c. I spend much of my time worrying about my health.
   d. I spend most of my time worrying about my health.

2. a. I notice aches/pains less than most other people (of my age).
   b. I notice aches/pains as much as most other people (of my age).
   c. I notice aches/pains more than most other people (of my age).
   d. I am aware of aches/pains in my body all the time.

3. a. As a rule I am not aware of bodily sensations or changes.
   b. Sometimes I am aware of bodily sensations or changes.
   c. I am often aware of bodily sensations or changes.
   d. I am constantly aware of bodily sensations or changes.

4. a. Resisting thoughts of illness is never a problem.
   b. Most of the time I can resist thoughts of illness.
   c. I try to resist thoughts of illness but am often unable to do so.
   d. Thoughts of illness are so strong that I no longer even try to resist them.

5. a. As a rule I am not afraid that I have a serious illness.
   b. I am sometimes afraid that I have a serious illness.
   c. I am often afraid that I have a serious illness.
   d. I am always afraid that I have a serious illness.

6. a. I do not have images (mental pictures) of myself being ill.
   b. I occasionally have images of myself being ill.
   c. I frequently have images of myself being ill.
   d. I constantly have images of myself being ill.

7. a. I do not have any difficulty taking my mind off thoughts about my health.
   b. I sometimes have any difficulty taking my mind off thoughts about my health.
   c. I often have any difficulty taking my mind off thoughts about my health.
   d. Nothing can tame my mind off thoughts about my health.

8. a. I am lastingly relieved if my doctor tells me there is nothing wrong.
   b. I am initially relieved but the worries sometimes return later.
   c. I am initially relieved but the worries always return later.
   d. I am not relieved if my doctor tells me there is nothing wrong.

9. a. If I hear about an illness I never think I have it myself.
   b. If I hear about an illness I sometimes think I have it myself.
   c. If I hear about an illness I often think I have it myself.
   d. If I hear about an illness I always think I have it myself.

10. a. If I have a bodily sensation or change I rarely wonder what it means.
    b. If I have a bodily sensation or change I often wonder what it means.
    c. If I have a bodily sensation or change I always wonder what it means.
    d. If I have a bodily sensation or change I must know what it means.

11. a. I usually feel at very low risk for developing a serious illness.
    b. I usually feel at fairly low risk for developing a serious illness.
    c. I usually feel at moderate risk for developing a serious illness.
    d. I usually feel at high risk for developing a serious illness.

12. a. I never think I have a serious illness.
    b. I sometimes think I have a serious illness.
    c. I often think I have a serious illness.
    d. I usually think that I am seriously ill.

13. a. If I notice an unexplained bodily sensation I never do anything to try to get rid of it.
    b. If I notice an unexplained bodily sensation I sometimes try to get rid of it.
    c. If I notice an unexplained bodily sensation I often try to get rid of it.
    d. If I notice an unexplained bodily sensation I always try to get rid of it.

14. a. My family/friends would say I do not worry enough about my health.
    b. My family/friends would say I have a normal attitude to my health.
    c. My family/friends would say I worry too much about my health.
    d. My family/friends would say I am a hypochondriac.

For the following questions, please think about what it might be like if you had a serious illness of a type which particularly concerns you (such as heart disease, cancer, multiple sclerosis and so on). Obviously you cannot know for definite what it would be like; please give your best estimate of what you <u>think</u> might happen, basing your estimate on what you know about yourself and serious illness in general.

15. a. If I had a serious illness I would still be able to enjoy things in my life quite a lot.
    b. If I had a serious illness I would still be able to enjoy things in my life a little.
    c. If I had a serious illness I would be almost completely unable to enjoy things in my life.
    d. If I had a serious illness I would be completely unable to enjoy life at all.

16. a. If I developed a serious illness there is a good chance that modern medicine would be able to cure me.
    b. If I developed a serious illness there is a moderate chance that modern medicine would be able to cure me.
    c. If I developed a serious illness there is a very small chance that modern medicine would be able to cure me.
    d. If I developed a serious illness there is no chance that modern medicine would be able to cure me.

17. a. A serious illness would ruin some aspects of my life.
    b. A serious illness would ruin many aspects of my life.
    c. A serious illness would ruin almost every aspect of my life.
    d. A serious illness would ruin every aspect of my life.

18. a. If I had a serious illness I would not feel that I had lost my dignity.
    b. If I had a serious illness I would feel that I had lost a little of my dignity.
    c. If I had a serious illness I would feel that I had lost quite a lot of my dignity.
    d. If I had a serious illness I would feel that I had totally lost my dignity.

Choose a number from the scale below to show how much you would avoid each of the situations listed below because of fear or other unpleasant feelings. Then write the number you chose in the space provided.

0.....1.....2.....3.....4.....5.....6.....7.....8

Would not avoid it	Slightly avoid it	Definitely avoid it	Markedly avoid it	Always avoid it

1. Consulting your family doctor....._____
2. Visiting a friend in hospital....._____
3. Visiting a relative in hospital....._____
4. Going to a hospital for treatment....._____
5. Talking about illness....._____
6. Reading about illness....._____
7. Visiting a hospital for other reasons (e.g. delivering a message)....._____
8. Watching TV programmes about illness....._____
9. Listening to radio programmes about illness....._____
10. Thinking about illness....._____

Choose a number from the scale below which best describes how often you seek reassurance about your health, from each of the sources described below. Then write the number you have chosen in the space provided.

0.....1.....2.....3.....4.....5.....6.....7.....8

Never	Rarely	Sometimes	Often	Daily

1. Friends....._____
2. Family....._____
3. Reading books....._____
4. Checking body for changes....._____
5. Family doctor....._____
6. Nurses....._____
7. Hospital outpatient clinic....._____
8. Hospital casualty....._____
9. Other (specify)....._____

Appendix D

Demographic Questionnaire

Demographic Questionnaire

Participant ID:

What age are you?

In the box, please write your age in years

What is your ethnic group?

Choose (tick) one option that best describes your ethnic group or background

White
English/Scottish/Northern Irish/Welsh/British
Irish
Gypsy or Irish Traveller
Any other white background, please described:
Mixed/Multiple ethnic groups
White and Black Caribbean
White and Black African
White and Asian
Any other Mixed/Multiple ethnic background, please describe:
Asian/Asian British
Indian
Pakistani
Bangladeshi
Chinese
Any other Asian background, please describe:
Black/African/Caribbean/Black British
African
Caribbean
Any other Black/African/Caribbean background, please describe
Other ethnic group
Arab
Any other ethnic group, please describe

What is your sexual orientation?

Choose (tick) one option that best describes your sexual orientation

Gay
Bisexual
Heterosexual
Any other sexual orientation, please described:

What is your marital status?

Choose (tick) one option that best describes your marital status

Single
Partnered
Married
Divorced
Any other marital status, please describe:

What is your highest educational qualification?

Choose (tick) one option that best describes your highest educational qualification

None
GCSE
A-levels
Bachelor's degree
Postgraduate
Any other educational qualification, please describe:

What is your occupation?

Please write in the box below

How long have you been using PrEP?

Years: Months:

How do you take your PrEP?

Choose (tick) one option that best describes how you take PrEP

Daily
Event based dosing/On demand/Intermittent/ 2-1-1
Any other dosing regime, please describe:

How do you access PrEP?

Choose (tick) one option that best describes how you source PrEP

Buy online
Private health provider
IMPACT trial
Any other source, please describe:

Appendix E

Topic Guide

[redacted]

Interview Topic Guide

The experiences of non-high risk men who have sex with men who are using HIV pre-exposure prophylaxis (PrEP)

Research Questions:

1. What are the reasons for non-high risk MSM deciding to start using PrEP?
2. What impact does using PrEP have on non-high risk MSM's perceptions of their risk of HIV?
3. What are the psychological and psychosexual impacts on non-high risk MSM using PrEP?
4. Is there a difference between those who have high levels of health anxiety and those who do not?

(a) Introduction, overview of research, and confidentiality (~5 minutes):

- Welcome and introduction to researcher;
- Instructions regarding the interview: **We are interested in the experiences of relatively low risk men who have sex with men's experiences of using PrEP. In particular, to find out why you started using prep, what impact it has had on you with regards to how you think about your HIV risk, as well as the psychological and psychosexual impact.**
- Confidentiality: Outline the scope and limitations of confidentiality. **Confidentiality will only be broken in exceptional circumstances if there are significant grounds for concern about a response given, and this would be discussed with you beforehand. You have the option to withdraw from the interview throughout.**

(b) Initiation of PrEP (~5-10 minutes):

- Reasons for starting PrEP?
    i. Probe: anxiety; beliefs around responsibility (to self and others); peer pressure
- Length of use
- Regime
    i. Probe: rationale; self-efficacy
- Sourcing
    i. Probe: safety

(c) Health Anxiety (~10 minutes):

- Preoccupation
    i. Probe: time spent thinking about HIV

- Symptom interpretation
    i. Probe: seroconversion/primary HIV infection symptoms
- Health anxiety levels, easy alarmed
    i. Probe: risks
- Excessive health-related behaviours
    i. Probe: body checking; frequent testing; avoidance.

(d) HIV Risk perception (~10 mins)

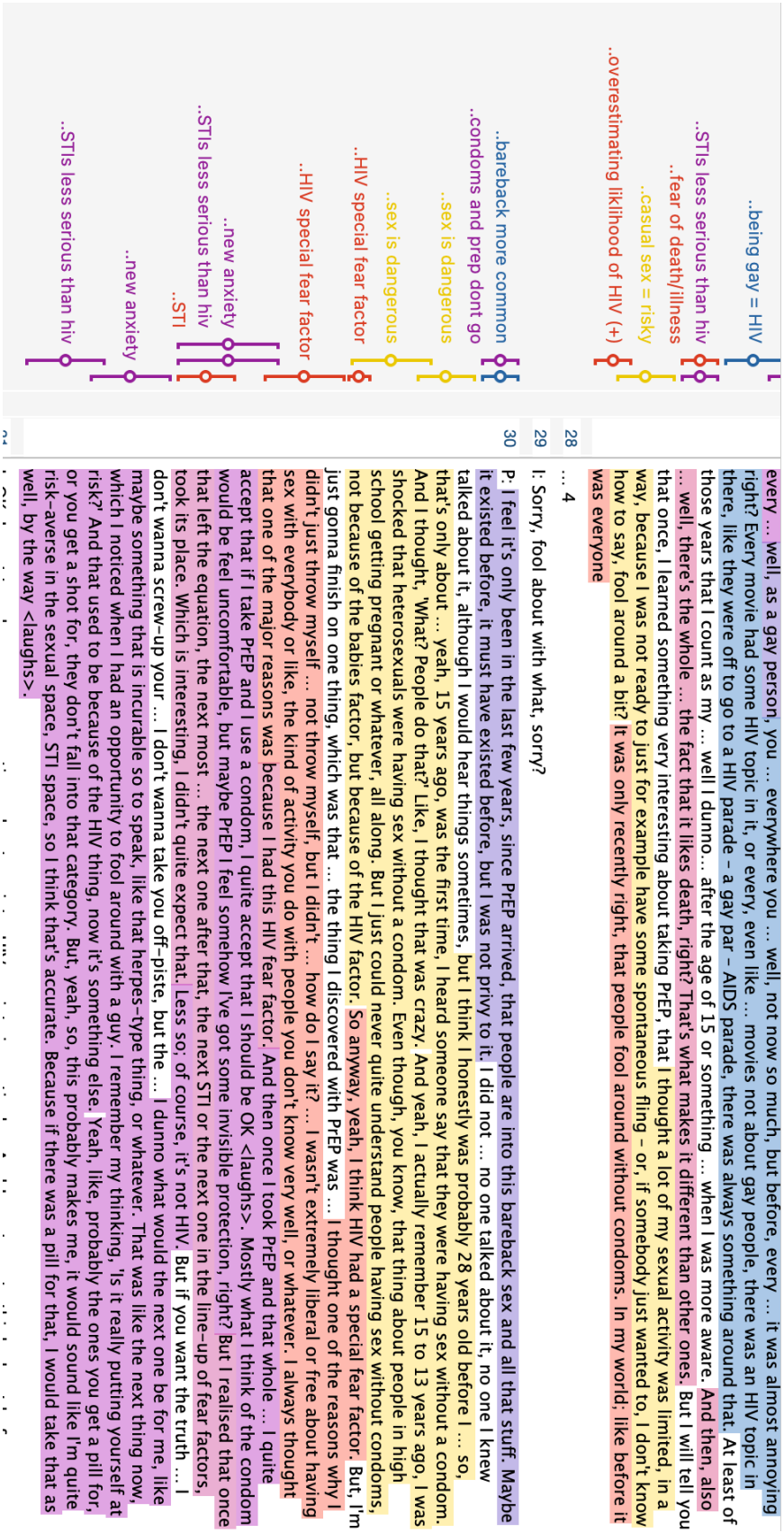
- Prior to taking PrEP…
    i. Probe: likelihood of diagnosis; perceived vulnerability
- On PrEP…
    i. Probe: likelihood of diagnosis; perceived vulnerability
    ii. Probe: risk/experiences of other infections

(e) Psychological and psychosexual impact (~20 minutes) :

- Anxiety
    i. Probe: trajectory of anxiety (if present), different from before; management of anxiety; intensity of anxiety
- Sexual behaviour (before and after)
    i. Probe: number of partners; partner selection; sexual activity; condom use; chems/drugs; sexual satisfaction; receptive anal sex
- Identity/image as a gay man
    i. Probe: liberation; promiscuous; responsible

Appendix F

Coding Example



every ... well, as a gay person, you ... everywhere you ... well, not now so much, but before, every ... it was almost annoying right? Every movie had some HIV topic in it, or every, even like ... movies not about gay people, there was an HIV topic in there, like they were off to go to a HIV parade – a gay par – AIDS parade, there was always something around that. At least of those years that I count as my ... well I dunno... after the age of 15 or something ... when I was more aware. And then, also ... well, there's the whole ... the fact that it likes death, right? That's what makes it different than other ones. But I will tell you that once, I learned something very interesting about taking PrEP, that I thought a lot of my sexual activity was limited, in a way, because I was not ready to just for example have some spontaneous fling – or, if somebody just wanted to, I don't know how to say, fool around a bit? It was only recently right, that people fool around without condoms. In my world; like before it was everyone

... 4

I: Sorry, fool about with what, sorry?

P: I feel it's only been in the last few years, since PrEP arrived, that people are into this bareback sex and all that stuff. Maybe it existed before, it must have existed before, but I was not privy to it, I did not ... no one talked about it, no one I knew talked about it, although I would hear things sometimes, but I think I honestly was probably 28 years old before I ... so, that's only about ... yeah, 15 years ago, was the first time, I heard someone say that they were having sex without a condom. And I thought, 'What? People do that?' Like, I thought that was crazy. And yeah, I actually remember 15 to 13 years ago, I was shocked that heterosexuals were having sex without a condom. Even though, you know, that thing about people in high school getting pregnant or whatever, all along. But I just could never quite understand people having sex without condoms, not because of the babies factor, but because of the HIV factor. So anyway, yeah, I think HIV had a special fear factor. But, I'm just gonna finish on one thing, which was that ... the thing I discovered with PrEP was ... I thought one of the reasons why I didn't just throw myself ... not throw myself, but I didn't ... how do I say it? ... I wasn't extremely liberal or free about having sex with everybody or like, the kind of activity you do with people you don't know very well, or whatever. I always thought that one of the major reasons was because I had this HIV fear factor. And then once I took PrEP and that whole ... I quite accept that if I take PrEP and I use a condom, I quite accept that I should be OK <laughs>. Mostly what I think of the condom would be feel uncomfortable, but maybe PrEP I feel somehow I've got some invisible protection, right? But I realised that once that left the equation, the next most ... the next one after that, the next STI or the next one in the line-up of fear factors, took its place. Which is interesting, I didn't quite expect that. Less so; of course, it's not HIV. But if you want the truth ... I don't wanna screw-up your ... I don't wanna take you off-piste, but the ... I dunno what would the next one be for me, like maybe something that is incurable so to speak, like that herpes-type thing, or whatever. That was like the next thing now, which I noticed when I had an opportunity to fool around with a guy. I remember my thinking, 'Is it really putting yourself at risk?' And that used to be because of the HIV thing, now it's something else. Yeah, like, probably the ones you get a pill for, or you get a shot for, they don't fall into that category. But, yeah, so, this probably makes me, it would sound like I'm quite risk-averse in the sexual space, STI space, so I think that's accurate. Because if there was a pill for that, I would take that as well, by the way <laughs>.

Appendix G

Research Ethics Committee (REC) Approval

Health Research Authority

London - Camberwell St Giles Research Ethics Committee
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0207104 8204

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

30 January 2020

Mr Christopher P McCormack
Trainee Clinical Psychologist
Essex Partnership University NHS Foundation Trust
The Lodge, Runwell Chase
Runwell
Essex
SS11 7XX

Dear Mr McCormack

Study title:	**The experiences of non-high risk men who have sex with men (MSM) who are using pre-exposure prophylaxis (PrEP)**
REC reference:	**19/LO/1954**
IRAS project ID:	**266963**

Thank you for your response received on 13th January 2020, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]	V1	01 August 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]	V2	01 August 2019
Interview schedules or topic guides for participants [Topic Guide]	V1	31 October 2019
IRAS Application Form [IRAS_Form_19112019]		19 November 2019
IRAS Checklist XML [Checklist_13012020]		13 January 2020
Letter from sponsor [Sponsor Letter]	V1	18 November 2019
Non-validated questionnaire [Demographic Questionnaire]	V1	21 November 2019
Other [Email from applicant responding to queries]		12 January 2020
Participant consent form [Consent Form V2]	V2	07 January 2020
Participant information sheet (PIS) [PIS GSTT V2]	V2	07 January 2020
Participant information sheet (PIS) [PIS CW V2]	V2	07 January 2020
Research protocol or project proposal [Protocol]	V0.2	31 October 2019
Summary CV for Chief Investigator (CI) [CV CMcCormack]	V1	
Summary CV for student [CV CMcCormack]	V1	
Summary CV for supervisor (student research) [CV Green]	V1	
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow Chart]	V1	18 November 2019

Validated questionnaire [HAI-18]	V1	

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

19/LO/1954	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Pp

Mr John Richardson
Chair

Email: nrescommittee.london-camberwellstgiles@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Sarah Manning-Press

Appendix H

Health Research Authority (HRA) Approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mr Christopher P McCormack
Trainee Clinical Psychologist
Essex Partnership University NHS Foundation Trust
The Lodge, Runwell Chase
Runwell
Essex
SS11 7XX

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

30 January 2020

Dear Mr McCormack

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**The experiences of non-high risk men who have sex with men (MSM) who are using pre-exposure prophylaxis (PrEP)**
IRAS project ID:	**266963**
REC reference:	**19/LO/1954**
Sponsor	**University of Essex**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **266963**. Please quote this on all correspondence.

Yours sincerely,

Natalie Wilson
Approvals Manager

Email: nrescommittee.london-camberwellstgiles@nhs.net

Copy to: *Ms Sarah Manning-Press, University of Essex, Sponsor*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]	V1	01 August 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]	V2	01 August 2019
Interview schedules or topic guides for participants [Topic Guide]	V1	31 October 2019
IRAS Application Form [IRAS_Form_19112019]		19 November 2019
IRAS Checklist XML [Checklist_13012020]		13 January 2020
Letter from sponsor [Sponsor Letter]	V1	18 November 2019
Non-validated questionnaire [Demographic Questionnaire]	V1	21 November 2019
Organisation Information Document [Master]	1	15 November 2019
Other [Email from applicant responding to queries]		12 January 2020
Participant consent form [Consent Form V2]	V2	07 January 2020
Participant information sheet (PIS) [PIS GSTT V2]	V2	07 January 2020
Participant information sheet (PIS) [PIS CW V2]	V2	07 January 2020
Research protocol or project proposal [Protocol]	V0.2	31 October 2019
Schedule of Events or SoECAT [Master]	1	02 December 2019
Summary CV for Chief Investigator (CI) [CV CMcCormack]	V1	
Summary CV for student [CV CMcCormack]	V1	
Summary CV for supervisor (student research) [CV Green]	V1	
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow Chart]	V1	18 November 2019
Validated questionnaire [HAI-18]	V1	

IRAS project ID	266963

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Research activities and procedures.as per the protocol and other study documents will take place at participating NHS organisations.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	Sponsor is not providing funding to participating NHS organisations.	A Local Collaborator (LC) is expected at participating NHS organisations.	Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix I

31st January 2020

Mr Christopher McCormack
Trainee Clinical Psychologist
Essex Partnership University NHS Foundation Trust
The Lodge, Runwell Chase
Runwell
Essex SS11 7XX

Dear Christopher,

Letter of Access for Research

This letter should be presented to your nominated manager at each participating site within this organisation before you commence your research at [redacted]

In accepting this letter, [redacted] confirms your right of access to conduct research through this organisation for the purpose and on the terms and conditions set out below. This right of access commences on **31st January 2020** and ends on **1st January 2021** unless terminated earlier in accordance with the clauses below. **If you require an extension to your letter of access, you must inform the Research and Development office, at least one month in advance.**

This letter of access is for research activities in relation to the following **only**:

Study title:	**The experiences of non-high risk men who have sex with men (MSM) who are using pre-exposure prophylaxis (PrEP)**
IRAS reference:	**266963**
REC reference:	**19/LO/1954**
Local reference:	**C&W19/081**

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from [redacted]. Please

note that you cannot start the research until the Principal Investigator for the research project has received a letter from the department of research and development giving confirmation of their agreement to conduct the research.

The information supplied about your role in research at this organisation has been reviewed and you do not require an honorary research contract with this organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out. Evidence of checks should be available on request to this organisation.

You are considered to be a legal visitor to the organisation premises. You are not entitled to any form of payment or access to other benefits provided by [redacted] to employees and this letter does not give rise to any other relationship between you and this organisation, in particular that of an employee.

While undertaking research through this organisation you will remain accountable to your substantive employer but you are required to follow the reasonable instructions of this organisation or those instructions given on their behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with this organisation's policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with this organisation in discharging its duties under the Health and Safety at Work Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on the organisations premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and Chelsea and Westminster Hospital NHS Foundation Trust prior to commencing your research role.

You are required to ensure that all information regarding patients or staff remains secure and **strictly confidential** at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on this organisations premises you wear your ID badge

at all times, or are able to prove your identity if challenged. Please note that this organisation does not accept responsibility for damage to or loss of personal property.

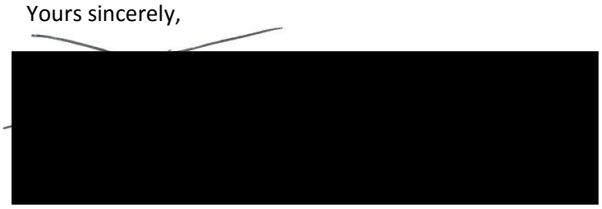
This organisation may revoke this letter and terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you **must stop** undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

No organisation will indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager [redacted] in this organisation and the department of research and development in this organisation.

Yours sincerely,



Appendix J

[redacted]

GSTFT ref: **LOA 1035**

Date: 31st January 2020

Dear Mr McCormack,

Letter of access for:	**The experiences of non-high risk men who have sex with men (MSM) who are using pre-exposure prophylaxis (PrEP)**
IRAS Reference:	**266963**
REC Reference:	**19/LO/1954**

This letter should be presented to [redacted] research team before you commence your research at that site.

In accepting this letter, [redacted] confirms your right of access to conduct research through the organisation for the purpose and on the terms and conditions set out below. This right of access commences on **31/01/2020** and ends on **01/04/2021** (the palnned end date of the study) unless terminated earlier in accordance with the clauses below.

As an existing NHS employee you do not require an additional honorary research contract with the participating organisation(s). The organisation(s) is/are satisfied that the research activities that you will undertake in the organisation(s) are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this organisation that the necessary pre-engagement checks are in place in accordance with the role you plan to carry out in the organisation(s). Evidence of checks should be available on request to [redacted]

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving the organisation(s) permission to conduct the project.

You are considered to be a legal visitor to [redacted] Trust premises. You are not entitled to any form of payment or access to other benefits provided by [redacted] to employees and this letter does not give rise to any other relationship between you and [redacted], in particular that of an employee.

While undertaking research through [redacted], you will remain accountable to your employer, **Essex Partnership University NHS Foundation Trust**, but you are required to follow the reasonable instructions of the Principal Incestigator ([redacted] or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by [Insert organisation] or this organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with [redacted] policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with [redacted] in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on [redacted] premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and each participating [Insert organisation] prior to commencing your research role at each site.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 2018. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

The organisation(s) will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 2018. Any breach of the Data Protection Act 2018 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that the organisation(s) accept no responsibility for damage to or loss of personal property.

This letter may be revoked and your right to attend the organisation(s) terminated at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of the organisation(s) or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or suitability to work with adults or children, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the organisation that employs you through its normal procedures. You must also inform the nominated manager in each participating organisation..

Yours sincerely

Appendix K

Amendment Confirmation

Notice of Amendment IRAS Version 5.13

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Low risk gay men who are using PrEP: A qualitative study Version 1.0

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
(●) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
◯ Scotland
◯ Wales
◯ Northern Ireland
◯ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

◯ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ◯ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

◯ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◯ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This is a student-led project as part of doctoral qualification clinical psychology. The student will be the Chief Investigator.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Mr	Christopher P	McCormack
Work Address	The Lodge, Runwell Chase		
	Runwell		
	Essex		
PostCode	SS11 7XX		
Email	christopher.mccormack@nhs.net		
Telephone	07401554567		
Fax	00000000000		

For guidance on this section of the form refer to the guidance

Full title of study:	The experiences of non-high risk men who have sex with men (MSM) who are using pre-exposure prophylaxis (PrEP)
Lead sponsor:	University of Essex
Name of REC:	
REC reference number:	

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	[redacted]
Date study commenced:	1 February 2020
Protocol reference (if applicable), current version and date:	V2.0 27 April 2020
Amendment number and date:	Amendment number 1, 27 April

Type of amendment

(a) Amendment to information previously given in IRAS

◉ Yes ○ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

◉ Yes ○ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

○ Yes ◉ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

Interview transcription (A41).
Currently, the interview transcription is carried out by Mr Christopher McCormack (Chief Investigator). We would like permission to use a professional transcription service.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
Consent Form	V2.1	30/04/2020
Participant Information Sheet	V2.1	27/04/2020
Protocol	V2.0	27/04/2020

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Mr Christopher McCormack on 07/05/2020 14:04.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Essex Partnership University NHS Foundation Trust
Email:	christopher.mccormack@nhs.net

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Sarah Manning-Press on 07/05/2020 14:30.

Job Title/Post:	Research Governance and Planning Manager
Organisation:	University of Essex
Email:	sarahm@essex.ac.uk

Appendix L

Critical Appraisal of the Current Study

Table L1

CASP quality appraisal of the current study

Quality Appraisal Criteria									
Clear statement of Aims?	Qualitative methodology appropriate?	Appropriate research design?	Appropriate recruitment strategy?	Appropriate data collection?	Relationship between researcher and participants considered?	Consideration of ethical issues?	Rigorous data analysis?	Clear statement of findings?	How valuable is the research? *
2	2	2	2	2	2	2	2	2	

Note. * contribution of the study to existing knowledge, consideration of findings in relation to current practice, policy, or literature base, areas identified for further research, transferability of findings discussed; 2 = yes; 1 = can't tell; 0 = no