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The acceptability of pre-exposure HIV prophylaxis in men who have sex with
men in London.

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Abstract

Men who have sex with men (MSM) remain the group with the highest incidence of HIV in the UK, with a high concentration of infections in London.

Multi-site safety and efficacy trials have demonstrated significant reductions in HIV acquisition among MSM when prescribed a daily pre-exposure prophylaxis (PrEP). Success translating these scientific developments into effective prevention interventions requires an understanding of how acceptable they are to individuals at risk of HIV acquisition.

This thesis reports on the findings of twenty in-depth semi-structured qualitative interviews with MSM in London. To participate, men must have had at least one episode of sex without condoms with a known sero-discordant partner or a partner of unknown HIV status in the twelve months prior to interview.

The acceptability of a range of PrEP methods were explored, including daily and intermittent oral; topical; and injectable formulations of PrEP and the potential impact of PrEP use upon men's perceptions of risk and behaviours.

Dimensions of acceptability draw on the personal (such as side effects; increased or diminished HIV vulnerability; adherence to drug/medical regimes); the inter-personal (such as negotiation of sex; stigma or discrimination); and community or social concepts of acceptability (such as financial burden and concepts of increased 'community risk').

The thesis provides a framework for understanding PrEP acceptability, showing that concepts of acceptability are complex and that the different dimensions of acceptability are inter-related.

The thesis concludes with recommendations for future policy and service delivery of PrEP to at-risk groups in the UK.

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Glossary

ART	Anti-retroviral therapies
CAPRISA 004	South African based study assessing the effectiveness and the safety of a vaginal gel
DrPH	Doctor of Public Health
ECDC	European Centre for Disease Control
FDA	Federal Drug Administration (USA)
Ipergay	Intervention Prophylactique pour Et avec les Gays. The first study to explore the efficacy of non-daily oral PrEP
iPREX	Multi-national Phase III trial exploring efficacy of daily oral PrEP in MSM and transgender women
iPREX OLE	Open label extension of iPREX
MSM	Men who have sex with men. A behavioural definition that encompasses all men who are or have had sex with men, regardless of their sexual identity or orientation
OPA	Organisational Policy Analysis
PEP	Post exposure prophylaxis
PrEP	Pre exposure prophylaxis
PROUD	England based study exploring the effectiveness of daily oral PrEP in MSM and transgender women
STI	Sexually transmitted infection
SWC	Sex without condoms
Topical PrEP	In the context of this thesis topical PrEP is taken to mean any foam, gel or non-solid substance that is inserted into or applied to the body for the purpose of preventing HIV
Transgender	Someone whose gender identity is not that assigned to them at birth
TasP	Treatment as Prevention – the concept that HIV drugs used to treat HIV infection can also prevent onward transmission of HIV from someone with HIV
WHO	World Health Organisation

Integrating Statement

LSHTM's Doctor of Public Health programme seeks to equip and skill leaders or future leaders in the public health field. As a previous leader within the field of HIV prevention in the UK, and unlike many of my contemporaries on the programme, I had the sense that I already had a proven track record of leadership and management within this particular public health discipline, but lacked the academic and intellectual robustness to break through the glass-ceiling of the career pathways of that field. For many other students, especially those who had followed the traditional trajectory from undergraduate, to Masters and then doctoral level studies, there was a sense that it was leadership experience in public health that was lacking, rather than academic rigour.

At the time of my enrolment, students took two five week modules in Evidence Based Public Health Practice (EBPHP), and one five week module in Leadership and Management and Personal Development (LMPD) - a requirement that had shifted to two five week modules by the time I started that course, in my second year - followed by a selection of courses from the School's MSc programme.

EBPHP furnished me with a raft of knowledge and skills that stretched my thinking and challenged my (then) practice as a public health practitioner. Training in undertaking systematic reviews and debates around the use of evidence challenged my notions and belief in the foundations of the practice I was undertaking at the time and, in part, contributed to a decision to move on from that practice. Undertaking the systematic review assignment, was one of my most intellectually challenging academic experiences, and set a high bar for my expectations for the rest of the programme. Conversely, the modules of the course that addressed public health policy and its use in practice reassured me of the skills I was already putting to use – and I sailed through the assignment on developing policy and applying policy in public health practice. On reflection, the sessions on how the media interpret and use evidence, and how to talk to journalists, seem to be a crucial element of how a modern public health leader operates.

LMPD offered a more reflexive and 'softer' but no less challenging accompaniment to EBPHP. The theoretical concepts of (change) management and leadership provided an essential grounding for the work to follow in the Organisational and Policy Analysis

(OPA). The modules providing techniques and tools for management and leadership within work settings accompanied and complimented the on-the-job leadership training and experience I had been exposed to within my work place. Aside from the theoretical and practical approaches, having the time and opportunity to reflect, debate, explore and nurture some of the opportunities and challenges of leadership provided a valuable learning and development opportunity. Going through a ten-week process of personal development and reflection, alongside my peers, was both a privilege (when else do we have the time out for such opportunities?) and an honour. This opportunity can only happen when individuals involved make the commitment to participate – both through time and willingness – and when the interaction happens face-to-face. Despite debates as to whether some elements of the programme could happen through Distance Learning, I can categorically say that the benefits of this course can only be attained through knowing and trusting your peer group directly, rather than virtually.

The (at the time) compulsory Masters modules gave me insight in to the School's teaching programme and methods of assessing students. Arguably, opting for more skills based courses, such as qualitative research skills, rather than subject based courses, might have increased my learning and development, but the courses were 'Masters level' and my two major reflections on those modules were i/ that they reflected how exceptionally well taught and 'top level' the dedicated DrPH taught modules were (i.e. the difference between the standard of DrPH and Masters courses were stark) and ii/ they provided me with an in-road to teaching on a range of in-house Masters modules and module organising on Distance Learning Masters courses: an unforeseen but very welcome career development outcome of being a student on those courses.

A further unplanned and unforeseen benefit of being a self-funded student within the School was the opportunity to place myself within research projects and studies that honed and refined my research skills. An early opportunity to work alongside Professor Kaye Wellings on a study of attitudes to blood donation in men who have sex with men in the UK provided me with on-the-job development and training in qualitative field work, navigating ethics approval and publication, as second author, in my first peer-reviewed journal article. Furthermore, it gave me the opportunity to bring my previous experience of engaging with stakeholder organisations in research dissemination, into

that research team. I would strongly recommend that future DrPH students are made aware of and know the development benefits of being ingrained in the teaching and research opportunities within the School, especially when those opportunities assist in preparation for research skills that will be needed in the final thesis.

That qualitative fieldwork experience allowed for a fairly smooth transition into developing a research protocol, and undertaking field work, using a broad range of qualitative methods for the OPA undertaken at San Francisco Aids Foundation. Preparation for the OPA raised the particular challenges of being a part-time student, not least because the compulsory DrPH modules running concurrently in the autumn term mean that part-time students, having completed one module, had to wait for a further nine months before completing the further module that fully equips them to undertake the OPA. In retrospect, taking the taught modules full-time for one term would have been a more efficient path to follow and one that I would strongly recommend to future students.

The opportunities and challenges of undertaking the OPA are partially addressed in the OPA report itself and have been reviewed on a number of occasions with the DrPH Course Director since then. In addition to that commentary, arriving in an organisation and in a City during a period of such fundamental change (the resignation of the CEO, the introduction of a new public health strategy respectively) was fortuitous, even if it muddied the focus of my original research questions. The OPA gave me the opportunity to fine-tune my qualitative research skills and to get in to the rhythm of academic writing. Most importantly, learning to balance the fine line between being an observer and a participant, and where to draw those boundaries, was the biggest asset that I took from the experience.

The final thesis has been the moment when my previous practitioner experience and the time spent on the DrPH programme have aligned most starkly. Having previously commissioned research, recruited to research projects, been the recipient of research (as a practitioner) and been a research participant, I have been more cognisant of my research participants as both end-users of that research and as true participants, rather than research subjects. Attempting to ‘bring along’ a number of participants, and other key stake holders – such as commissioners and providers who might benefit from the

results of the research – has brought challenges about when to ‘release’ findings, as has the challenge of studying within an institution that tends to be more driven by academic journal outputs rather than the iterative release and discussion of findings with practitioner colleagues. The final stages of the programme have been enthralling, experiencing the elements of the programme come together and observing the potential for driving that learning further.

A more general reflection on the programme surrounds the position it holds within the School. On-going attempts by students, course coordinators and administrators to enhance the kudos, awareness of, and interest in the DrPH programme have been undertaken, yet it still seems that the DrPH programme is viewed as a ‘poor relation’ to a PhD within the School. Recent attempts – driven by students – to shift that focus appear to have had limited progress and, to draw on the theoretical learning of organisational change from LMPD, could benefit from more transformational, rather than transactional, leadership approaches from within the School’s hierarchy.

Finally, from a broader developmental perspective for research degree students across the School, there is a current emphasis on development opportunities for early-career researchers. Yet far less emphasis is given for those of us, especially mature students, who have already developed or had a career and are looking for directions that do not follow a traditional academic pathway.

Chapter 1: Introduction

This thesis sets out to explore how acceptable pre-exposure HIV prophylaxis (PrEP) might be to men who have sex with men (MSM) in London who are at risk of HIV acquisition. It explores personal dimensions of PrEP acceptability, and how those personal dimensions are influenced and impacted by inter-personal and community or societal acceptability of PrEP. It provides a comparative analysis of PrEP acceptability by different PrEP methods, and considers how future HIV prevention policy, research and health promotion interventions should develop to incorporate PrEP.

PrEP is an HIV prevention technology that makes use of existing antiretroviral therapy to prevent HIV acquisition in uninfected individuals. This introductory chapter outlines the evidence of why MSM in London can be considered a priority population for PrEP provision in the UK, drawing on contemporary data from national HIV surveillance systems. It describes the HIV prevention successes of the last decade and highlights how current HIV prevention approaches, on their own, will likely fail to stem the onward transmission of HIV among MSM, before introducing the concept of how antiretroviral therapy has the potential to play a key role in future HIV prevention approaches. The chapter establishes the aim and objectives of this thesis and then sets out the structure of the subsequent chapters.

1.1 HIV infection among men who have sex with men – a public health concern

HIV infection resulting from sex between men accounts for the majority of UK-acquired HIV diagnoses (Yin et al., 2014). HIV diagnoses among MSM have risen steadily each year since 2001 and, despite a leveling-off during 2007-09, increased in 2010, accounting for 45% of total infections diagnosed - but not necessarily acquired – in the UK. Around one quarter of those infections are thought to have been recently acquired, with men under 35 accounting for one-third of those newly diagnosed who were recently infected (Health Protection Agency, 2011). In 2013, more than half of the UK's diagnosed HIV infections were amongst MSM with an estimated 43,500 MSM living with HIV in the UK (Yin et al., 2014). Public Health England estimates that around 7,000 MSM, or 16% of MSM with HIV, had not had their infection diagnosed (Yin et al., 2014). HIV prevalence in MSM in the UK is estimated to be 59 per 1,000 population compared with an estimated UK general population prevalence of 2.8 per

1,000. It is higher still in MSM in London where 1 in 8 MSM have HIV, compared with 1 in 26 MSM outside of London (Yin et al., 2014). Of key significance to this thesis are the large geographical variations, and the fact that HIV prevalence among MSM in London is more than three times higher than outside of London (1 in 8 vs. 1 in 26).

With early diagnosis of HIV infection and significant improvements in HIV anti-retroviral treatments, HIV infection in the UK is thought to have an insignificant impact on longevity of life. Mathematical models suggest that a non-smoking, 30-year old gay man who receives a prompt diagnosis after infection, has a life expectancy of 78 years, compared to a life expectancy of 82 for a man who does not have HIV (Nakagawa, 2011). However, the long-term impacts of HIV infection and HIV medication are uncertain; stigma and discrimination against people with HIV – in personal and sexual relationships, in medical settings, and from wider society – exist and can impact on the mental, sexual and physical health of a person with HIV (Bourne et al., 2009; Smit et al., 2012); and the costs of HIV medication, treatment and care have a significant impact on the National Health Service, with the lifetime costs of HIV treatments alone estimated to be between £280,000 and £360,000 per person (Select Committee on HIV and AIDS in the United Kingdom, 2011). As such, measures to prevent primary HIV infection remain essential, with a particular need to prioritise the prevention of HIV infection amongst MSM.

1.2 Preventing HIV transmission

Over the last three decades, significant activity has been undertaken to reduce HIV infection in the UK. Strategies for reducing HIV acquisition amongst MSM in England have focused on the concept of ‘best sex with least harm’ and have included raising awareness of HIV status and diagnosis of HIV; raising awareness, diagnosis and treatment of STIs; interventions that increase MSM’s knowledge of HIV, as well as its prevention and treatment; interventions that increase men’s skills to negotiate and have the sex they want; and interventions that facilitate increased awareness or risk reduction in environments where men meet for sex – such as the provision of information or condoms and lubricant (CHAPS Partnership, 2011).

There have been notable successes in HIV prevention activity (Sullivan et al., 2012); not least those that have been connected to increased levels of HIV testing (Yin, 2014).

Systematic reviews have identified evidence of behavioural interventions – including interpersonal skills training, multi-method interventions, and multiple interventions over durations of a minimum of 3 weeks - that have been shown to impact on HIV risk on an individual, group or community level (Herbst et al., 2005, Herbst et al., 2007, Johnson et al., 2002, Johnson et al., 2005). Yet, these interventions are costly to implement on a population level and resources to adequately scale-up these interventions have not been forthcoming. Indeed, structural impediments to implementing behavioural interventions, including opposition to school-based sex education and complex re-organisation of health service have further impacted upon behavioural implementation (Select Committee on HIV and AIDS in the United Kingdom, 2011). Additionally, behavioural-only interventions have been shown to be less acceptable, appropriate or feasible with many MSM, with international bodies, such as UNAIDS, making a strong case for combination prevention: prevention that combines behavioural, bio-medical and structural interventions (Buchbinder & Lui, 2011; Tatoud, 2011; UNAIDS, 2010).

1.3 Biomedical prevention: the emergence of PrEP

The last decade has witnessed significant scientific developments with regards to preventing HIV transmission using medical technologies. Anti-retroviral therapy, once thought of only in terms of maintaining the well-being of those already infected with HIV, is now emerging as a central component of HIV *prevention* efforts. Early treatment of people with HIV with anti-retrovirals has been found to lower the infected individual's HIV viral load (a measure of the amount of HIV in an individual's body fluids), and reduce onward transmission of HIV by up to 97% (Cohen et al., 2011) thus rendering them effectively uninfected. This has led to a reconstruction of anti-retroviral therapy as 'treatment as prevention' (Das Douglas et al., 2010; Lima et al., 2008; UNAIDS, 2011).

In addition to the use of anti-retroviral therapy to reduce viral load of those already infected, the same medication has been utilised to reduce the likelihood of HIV transmission to uninfected individuals who are exposed to HIV. This 'post exposure prophylaxis' (PEP) for individuals exposed to HIV has been utilised in medical settings following needle-stick and surgical injuries with protocols on occupational use developed internationally (Rey et al., 2000). Guidelines for the prescription of PEP for individuals who have been sexually exposed to HIV were introduced in England in

2006 (Fisher et al., 2006), along with a raft of health promotion interventions to increase knowledge and access to PEP amongst at-risk MSM (Terrence Higgins Trust, 2006).

Further to the notion of ‘treatment as prevention’ and PEP, there has been significant development of antiretroviral medication that can be used *prior* to HIV exposure that might prevent an HIV negative individual becoming infected. Termed ‘pre-exposure prophylaxis’ (PrEP), this is a biomedical technology that allows HIV uninfected individuals to control their susceptibility to HIV prior to exposure. Current scientific research is being undertaken that explores the safety and efficacy of PrEP in men in three different formats -

Oral PrEP - taken as a tablet either daily or intermittently

PrEP in a topical gel format - inserted vaginally or rectally (often termed ‘microbicides’)

PrEP in an injectable format

In addition, and not touched upon in this research, PrEP is also being explored in other formats such as cervical ring formats, for use by women during sex with men (Chen et al., 2014). For the purpose of this research, “PrEP” is used as a term to encompass all of the above formats.

1.4 Aims of the research

PrEP has demonstrated considerable promise in clinical trials as a means of preventing HIV infection among those most at risk of acquisition (Grant et al., 2010). If this technology is to be successfully integrated into existing HIV practice, it is imperative to better understand acceptability of PrEP among those to whom it will be targeted. As such, the aim of this research is:

To assess the acceptability of HIV pre-exposure prophylaxis (PrEP) amongst men who have sex with men (MSM) in London.

Objectives:

- To assess MSM’s knowledge and views of PrEP;

- To assess MSM's willingness to consider using PrEP, the factors contributing to willingness to use PrEP and barriers to using PrEP;
- To assess the relative acceptability of different PrEP delivery methods to MSM;
- To make recommendations for PrEP provision and for PrEP health promotion interventions that target MSM.

1.5 Structure of the thesis

Chapter 2 summarises the current evidence on the efficacy and effectiveness of PrEP from clinical trials, before moving on to establish some of the key social, economic and political constraints to the provision of PrEP. The chapter describes and discusses the central importance of acceptability of new HIV prevention technologies, if they are to be used by key at-risk populations, and summarises existing evidence on the acceptability of PrEP. The concept of acceptability is examined, within theoretical frameworks of risk, before an acceptability framework is proposed, that forms the basis of this thesis. The chapter concludes with a brief overview of how the fast-moving evidence base on PrEP is impacting on policy and practice, especially with regard to the timeframe in which fieldwork for this thesis was collected.

Chapter 3 sets out the methodology used in the study, with an explanation of why the research approach that was employed was deemed to be the most appropriate. The chapter explains the sampling method and describes the demographic profile of the men in the study, and how they were recruited. Ethical considerations and limitations of the study are also considered.

Chapter 4, the first results chapter, explores how men manage their sex lives. This context setting chapter explores how men 'do' sex and how they manage risk in the current absence of access to PrEP.

Chapter 5 explores the possible positioning of PrEP in men's lives – with a particular (and obvious) focus on men's sex lives. The chapter explores men's immediate willingness to use PrEP personally, including the dimensions of personal acceptability of daily oral PrEP, and then a comparative analysis by other PrEP methods.

Chapter 6 addresses perceived community and societal dimensions of PrEP and if and

how these perceptions impact on the extent to which men consider it personally acceptable. The chapter provides a focus on the impact of stigmatisation of risk and risk-taking and the resulting impact on PrEP acceptability.

Chapter 7 provides four case studies of individual men's perceptions of PrEP and the potential impact of PrEP use on their (sex) lives. The case studies highlight the dynamic nature of individual's PrEP beliefs, including their own inconsistencies in how PrEP might be used or considered.

Chapter 8 draws out and further discusses the key findings of this research, and how the thesis makes a unique contribution to the evidence on potential PrEP uptake and use among MSM. This discussion chapter focuses on the major findings from the research and concludes with a proposed model of PrEP acceptability.

The final chapter provides an overview of the key recommendations of this thesis and, given the applied nature of the doctorate in public health, the implications of these findings for future research, policy makers and HIV health promoters.

Chapter 2: Reviewing the evidence

In the chapter that follows I review the existing literature relevant to this research study. The chapter starts by reviewing the literature on PrEP itself, focusing on three different PrEP methods. Then follows a review of contemporary issues relating to the implementation of PrEP, establishing some of the key social, economic and political constraints to the provision of PrEP. The chapter continues by describing and discussing the central importance of acceptability of new HIV prevention technologies, if they are to be used by key at-risk populations, and to summarise existing evidence on the acceptability of PrEP. The concept of acceptability is examined, within theoretical frameworks of risk, before an acceptability framework is proposed that forms the basis of this thesis. The chapter concludes with a brief overview of how the fast-moving evidence base on PrEP is impacting on policy and practice, especially with regard to the timeframe in which fieldwork for this thesis was conducted.

2.1 Pre-exposure prophylaxis – the evidence base

2.1.1 Topical PrEP

Much of the early clinical research relating to PrEP focuses on topical application in the vagina. Conceptually, topical PrEP might act in a number of ways to prevent HIV (and other pathogen) infection, including providing a physical barrier to prevent pathogens reaching target cells; preventing replication of a virus once it has entered a cell; killing or disabling the pathogen; or enhancing the natural defences of the vagina, such as maintaining an acidic pH. While many early studies failed to demonstrate significant effectiveness in preventing HIV transmission from an infected male to an uninfected female (Van Damme, 2007), July 2010 saw publication of results from the CAPRISA 004 trial (Abdool Karim and Abdool Karim, 2010). This large, double blind randomised controlled trial explored the effectiveness and safety of tenofovir (a specific form of antiretroviral medication) as a vaginal microbicide and showed a reduction in HIV incidence of around a half among women consistently and correctly using the gel, with no evidence of HIV drug resistance.

Whilst the CAPRISA trial results show promise for future use as one HIV prevention method for women having vaginal intercourse, evidence for the use of topical PrEP to

prevent HIV during anal intercourse is less developed. In January 2012, recruitment commenced to the MTN 017 rectal microbicide trial – the first Phase II safety and acceptability trial of tenofovir gel reformulated for rectal use (Microbicide Trial Network, 2015). MTN 017 evaluated drug absorption, participant acceptability and safety of the reformulated tenofovir gel used daily, used before and after sex amongst 216 HIV negative MSM. To gauge acceptability of the gel, participants were asked about any side effects experienced, their preference for using the gel on a daily or intermittent basis, and whether they would consider using the gel in future to reduce HIV acquisition. Results from MTN 017 are expected at the start of 2016.

In addition, in 2014 the John Hopkins Institute announced US National Institute of Health funding to develop an antimicrobial solution, in a single dose rectal enema or douche format, for use prior to anal intercourse (John Hopkins Medicine, 2014). Further research has been undertaken to better understand preferences between rectal applicators among MSM, when used to apply placebo or tenofovir gel (Carballo-Diequez et al., 2014). Furthermore, “Project Gel” is a multi-stage trial exploring rectal microbicide acceptability, safety and adherence in young MSM in the USA (Project Gel, 2014). While evidence for the efficacy of topical PrEP is still not forthcoming, significantly more progress has been observed with oral PrEP.

2.1.2 Oral PrEP

Clinical progress in relation to the development of oral PrEP has been far more pronounced. Early safety trials on the effectiveness of using tenofovir in a pill form among HIV negative gay men at high risk of acquiring HIV suggested no safety concerns in prescribing anti-retroviral drugs to HIV uninfected men (Grohskopf, 2010). In this randomised control trial of 400 men in the USA, none of the men in the tenofovir arm became infected, whilst seven men on the placebo arm acquired HIV during the period of the trial.

In November 2010, results of the Pre-Exposure Prophylaxis Initiative (iPrEX) – a multinational, randomised, double-blind, placebo controlled, Phase III trial - found that a daily oral dose of Truvada (a combination of tenofovir and emtricitabine) reduced HIV acquisition by 44% and, in those who took the drugs as directed, by approximately 90% (Grant et al., 2010). This first large scale PrEP study in MSM explored safety and

efficacy of a daily dose of ART in just under 2,500 MSM and transgender women in eleven countries. The medication caused no major side effects and none of the participants developed resistance to the drug.

In 2012 an open-label extension of iPREX for MSM and transgender women who have sex with men (iPREX OLE, 2012) commenced with 1225 participants from the iPREX study being given the option of continuing to take daily oral Truvada. Of these, 847 opted to continue to take PrEP. To date, the trial has found no HIV infections in people taking four or more doses of Truvada a week, with evidence that those at greatest HIV risk are taking more PrEP, and are adhering better than those at lower risk (Grant, 2014).

Two European based studies have further reported on PrEP efficacy and effectiveness amongst MSM since the start of 2015. The PROUD study, conducted among 545 MSM and transgender women at sites in England, randomised participants into either an active arm, that took daily oral Truvada, or a deferred arm, that was given oral PrEP after 12 months following enrolment. In October 2014, PROUD was un-randomised, with all participants being offered PrEP, when the trial's independent Data and Safety Monitoring Committee recommended that the randomisation be halted, given the significant differences in HIV infection between the two arms. In February 2015, evidence was presented from PROUD that daily oral PrEP was 86% effective at preventing HIV. The trial found adherence to be high, side effects to be low and mostly tolerable when they did occur. No significant difference was found in sexually transmitted infection (STI) incidence between participants in the active and deferred arms, with preliminary data suggesting that there was only negligible difference in condom use between participants in each arm, although further analysis on this is expected (McCormack, 2015). Further qualitative data on experience of using PrEP and other factors, including disclosure of PrEP use and sexual negotiation is expected later in 2016.

Following the un-randomisation of the PROUD study, the French and Canadian Intervention Prophylactique pour et avec les Gays (Ipergay) study (Agency Nationale de recherches sur le SIDA et les Hepatites virales, 2012), was also un-randomised in November 2014, when its Data and Safety Monitoring Board reviewed HIV incidence

and found oral PrEP to be highly effective. Ipergay is the only study to report on the effectiveness of intermittent or event based oral PrEP. 350 participants were randomised to take two Truvada pills, or a placebo, between one day to two hours before they planned to have penetrative intercourse and then, if intercourse took place, to take another pill 24 hours after sex, and then a fourth pill 48 hours after intercourse. Investigators on Ipergay were keen to explore if adherence using intermittent dosing would be better than daily oral PrEP. Like the PROUD study, Ipergay reported that PrEP was 86% effective at preventing HIV (Molina, 2015).

Both PROUD and Ipergay continue as un-randomised studies.

It is worth noting that at the time of fieldwork for this thesis research, iPREX OLE had reported no findings. Recruitment for PROUD and Ipergay only commenced at the end of the fieldwork and no findings of these two studies had yet been released during the fieldwork.

2.1.3 Injectable PrEP

Finally, the first human trials of a once-a-month injectable formulation of PrEP reported in March 2012 that drug levels in participants were maintained at a high enough rate to offer sufficient protection against HIV infection. The London-based trial of 27 women and six men found few side-effects when a single injection of rilpivirine was administered to HIV uninfected participants (Jackson, 2012).

Since fieldwork for this thesis was completed, further and substantial progress has been made with injectable PrEP. Both Johnson and Johnson, and Glaxo-Smith-Klein have undertaken safety studies of monthly injectable PrEP (HIVPlusMag, 2013). A study of GSK1265744 (commonly referred to as GSK744), found that monthly injections offered 100% protection to monkeys against SHIV, and suggested that injections given on a three-monthly basis might be similarly protective (Andrew et al., 2013). The same drug, trialed on 47 individuals, was found to reach drug levels expected to be therapeutic within 3 days, with concentrations remaining high for a prolonged period, and declining slowly, offering a level of ‘forgiveness’ if a dose is delayed (Spreen et al., 2013; Highleyman, 2013). Phase 2 trials of GSK744 (in a trial named HPTN077) are progressing, and, although it is now known that GSK744 remains active in the body for

about 12 weeks, it is still not clear how effective it is at preventing HIV in humans (Newman, 2015). HPTN077 is likely to complete in mid-2017, with a degree of anticipation that injectable PrEP might be an option sooner than anticipated (Heitz, 2015), especially if the drug can be demonstrated to be as safe and better than existing oral PrEP methods (Cohen, 2014).

These studies add further weight to the body of evidence regarding PrEP efficacy and effectiveness and that prescription of PrEP to MSM at risk of HIV infection in the UK might be considered in the very near future. However, prior to such prescription occurring, there are a number of practical and economic issues that need addressing, and behavioural and social questions that need to be explored in order to support the addition of this promising medical technology to the toolbox of existing HIV prevention interventions in the UK.

2.2 PrEP: Implementation issues to consider

Having reviewed the existing literature on PrEP, there are a number of key areas worthy of consideration with regard to the implementation of PrEP. Studies and opinion pieces have raised questions about the ethics, cost-effectiveness and behavioural risk implications of PrEP (Cairns, 2014a; Cohen and Baden, 2012; Desai, 2008; Grant, 2006; Tuller, 2013). Some have queried the extent to which PrEP should be made widely available with others suggesting that countries with focused epidemics should target specific 'at-risk' groups (Livoti, 2012; Paxton et al., 2007; Peterson et al., 2006). The possible impact of PrEP on individual men's condom use via behavioural disinhibition (PrEP being used as a substitute for condoms in men wanting unprotected sex) and risk compensation has been highlighted (Evans, 2012; Golub, 2010; Yeung, 2012). A further area of debate and concern has been the implications of widespread PrEP prescription on future availability of anti-retrovirals for HIV treatment, should drug resistance develop if anti-retrovirals for prevention are used sub-optimally (Gibbs, 2011; Mellors, 2010). Further discussions have focused on the potential cost of PrEP (Gomez et al., 2012), particularly in resource-poor settings where those with diagnosed HIV are unable to access ARTs (Gibbs, 2011).

However, consideration of *all* of these is beyond the scope of a DrPH thesis and I have necessarily focused on one particular pressing issue for consideration. Despite the

growing data on the efficacy of PrEP to prevent HIV, the success of translating these scientific developments into effective scaled-up HIV prevention interventions in a diversity of settings requires an understanding of how *acceptable* they are to individuals at risk of HIV exposure. Understanding the acceptability of an intervention or programme is an essential element of its success. As Ayala and Elder (2011) identify, interventions developed without an understanding of their acceptability risk being poorly implemented, unsustainable and without the trust of the target group. They can increase health inequalities if they are inappropriate to the target group (Cooper et al., 2002). Without an understanding of how target populations perceive an intervention, how they envisage it might form part of their decision making in their sexual lives and, ultimately, how acceptable PrEP might be to men who may be offered it, we are uncertain of if, how, and when it will be utilised. This is even more pronounced given the potential side effects associated with PrEP (see below) and the stigma associated with HIV and sex between men.

Existing models of intervention effectiveness in sexual health promotion provide frameworks under which to better understand the importance of acceptability in intervention design and evaluation. Kirby's review of effective interventions to reduce teenage pregnancy identifies seventeen characteristics of interventions that can be applied to other interventions (Kirby, 2007). Similarly, the England-wide planning framework to reduce HIV during sex between men (CHAPS Partnership, 2011) articulates seven dimensions or qualities of an effective sexual health promotion intervention of which acceptability is one key quality. That is: how does the target regard the objectives of the intervention, particularly in that setting?

Prior UK studies of HIV medication adherence can help us to better understand why acceptability is an important component of future PrEP delivery. Among people with HIV on treatments who experienced problems using HIV drugs regularly, participants raised issues including side-effects of drugs; difficulties fitting treatment-taking into daily routines; and concerns surrounding loss of confidentiality when carrying or using treatments in public or in family-settings (Weatherburn et al., 2002, Weatherburn et al., 2009). Understanding similar issues regarding potential PrEP prescription assists in our understanding of the acceptability of those risks and concerns versus the benefits of PrEP to individuals, their sexual partners and communities.

2.3 Existing evidence on PrEP acceptability

Several studies have already briefly addressed certain aspects of PrEP knowledge and acceptability in the population of MSM in the UK, although the concept in general, in relation to PrEP, remains poorly defined (a point explored in more detail in section 2.6) and has thus been constructed differently by the studies described in this section. It is important to be mindful of how research undertaken outside of the UK might not be transferable to UK settings – not least for that conducted in lower or middle income settings, or those, such as the USA with health insurance systems.

Findings of a 2011 online survey of 1259 MSM in England (Sigma Research, 2011) provide initial data on the acceptability of PrEP among this group. Awareness of PrEP was generally low, with 80% of respondents having previously been unaware of PrEP. When asked to consider how they might use PrEP were it available in England, around half of men who had not tested HIV positive (52.4%) would consider using PrEP if they were offered it at a sexual health clinic; and more than half of men (54.9%) would prefer taking a daily pill to intermittent dosing (27.4%). Men with casual partners were slightly more likely to consider using PrEP and men with a regular partner with diagnosed HIV were no more likely to consider PrEP than other men.

In open-text response boxes to explain their position, respondents saw PrEP as being acceptable for those who were cognisant of their risk taking. However, they did not see PrEP as influencing their current sexual behaviour; rather, that PrEP offered a way of reducing the risks of and concerns about their current known risk taking. In other men, PrEP might offer them the chance to engage in sex that they currently deemed too risky. Others failed to see the benefit of PrEP either because of consistent condom use or because they were of the belief that they did not have unprotected sex with men with HIV.

However, this was an online survey with a self-selecting sample and, as a result, the potential of respondents to be more amenable to responding to HIV health promotion surveys introduces a potential selection bias. The survey offers respondents a limited capacity to report and respond to their attitudes to PrEP and, although it provides a useful initial insight in to the views of MSM in England about PrEP, it lacks the depth

of fuller qualitative research in to acceptability.

Findings from a cross-sectional survey of 842 HIV-negative men recruited in gay venues across London undertaken in 2011 suggest that around half of men would consider taking PrEP (Aghaizu, 2012), whilst a survey of 121 HIV-negative MSM attending a Manchester sexual health clinic undertaken in 2011-2012 found that over a third would be “very willing” to take PrEP (Thng et al., 2012). As with the Sigma Research survey, these surveys offer a limited capacity to report PrEP acceptability, and the settings in which they are undertaken capture the views of a limited cross-section of men. Also, their focus only on willingness to use PrEP represents only one possible dimension of acceptability.

Since fieldwork for this thesis was completed, further research on PrEP acceptability has been conducted in Scotland. In a cross-sectional survey of 17 gay commercial venues in Edinburgh and Glasgow (Young et al., 2013) around half of the 1393 men included in the analysis reported that they would consider taking PrEP on a daily basis. Those who would not consider taking PrEP tended to report that they did not consider their risk to be sufficient to warrant taking a daily pill, or they highlighted concerns with using medication to prevent HIV.

Frankis et al’s (2014) mixed method study on understanding PrEP acceptability from a range of sites in Scotland found that almost half of 929 MSM in a cross-sectional survey would be likely to use PrEP should it be available, with a further quarter of men being unsure, and just over a quarter saying that they would be unlikely to use PrEP. Focus groups of men diagnosed with HIV found concerns about the potential costs of PrEP to the NHS, along with concerns about side effects and adherence. Men with HIV also voiced fears about HIV negative men using condoms less frequently when using PrEP. HIV negative or untested men in focus groups shared concerns about major side effects. In semi-structured qualitative interviews, men who did not have HIV voiced cautious optimism about PrEP. The authors conclude that it is crucial to consider the social context and men’s existing risk reduction strategies and how these will impact upon men’s future PrEP uptake.

Further Scottish research exploring barriers to uptake and use of PrEP (as indicators of

acceptability) was published in late 2014 (Young et al., 2014) and reported on findings from focus groups and in-depth interviews with MSM and Africans, including HIV positive, HIV negative and untested individuals. Understanding of PrEP's effectiveness and the maintenance of adherence were viewed as barriers to PrEP uptake, and self-perception of being at low-risk for HIV transmission meant that few participants saw themselves as benefitting from PrEP. Concern about other people's condom use whilst using PrEP meant that many participants viewed PrEP unfavourably. The authors conclude that PrEP implementation needs to consider appropriate communication methods to take into account divergent HIV literacy, and to demonstrate how PrEP sits alongside and complements other strategies to manage HIV transmission.

A small number of studies have been undertaken with MSM in sero-discordant relationships in the USA (Brooks et al., 2011; Mimiaga et al., 2009) that broadly find PrEP to be acceptable, although acceptability remains ill-defined in those studies. A 2012 mixed-method study of males in sero-discordant and sero-concordant (positive/positive couples) in San Francisco found a relatively low acceptability in the sample of 164 couples (Saber et al., 2012). Men in the study articulated concerns about possible risk-compensation and the authors noted that a quarter of men in the study confused PrEP with PEP. As with the other US based studies, acceptability was not clearly defined within this study.

Young and McDaid's (2014) review of research on acceptability of treatment as prevention (TasP) and PrEP explored 27 studies that examined acceptability of TasP and/or PrEP. They concluded that acceptability of PrEP within randomised control trials was usually measured by individual adherence rates and that few studies explored issues of risk. They found limited evidence of how individual choice and actions are limited or facilitated by broader cultural or social contexts. It should be noted however that this review had a primary focus on TasP (given the existing literature at the time of the review).

Beyond the UK, a seven-country interview-administered and self-administered survey (Peru, Ukraine, India, Kenya, Botswana, Uganda and South Africa) of 1,750 potential PrEP users recruited in a wide range of locations found an overall willingness to adopt PrEP within key populations – including MSM – and this willingness extended to use

despite possible side-effects, the need for regular HIV tests and the possibility of having to pay for PrEP (Eisingerich et al., 2012). Most participants said they would use condoms in combination with PrEP and that the most preferred method of administration of PrEP would be through a bimonthly buttock injection, followed by a monthly injection in the arm. A daily pill and a pill before or after intercourse were the least preferred route of administration and – as many participants reported they might be likely to share their medication – the authors report that an injectable format of PrEP (administered by medical staff), if such an option becomes available, might be preferable to reduce medication sharing and to increase adherence.

A study of 45 MSM, transgender women and female sex workers in Peru, published in May 2011, found that the low-cost of PrEP for individuals was the most significant determinant of its acceptability. Participants reported that they would be more likely to use PrEP if it was low cost, had efficiency of 95%, had no side effects and could be taken just prior to sex, rather than on a daily basis (Galea et al., 2011). Further concerns were raised by participants with regard to potential sexual risk dis-inhibition, stigma and discrimination associated with taking PrEP, and concerns with mistrust of health care professionals.

A number of studies have explored the acceptability of oral and topical vaginal PrEP in Ghana (Guest et al., 2010), Uganda (Kamali et al., 2010) and USA amongst sexually active women (McGowan et al., 2011). Similarly to acceptability studies in MSM, a 2003 – 2004 acceptability trial of vaginal microbicide gel amongst women in Ghana concluded that “women found gel use highly acceptable” (Guest et al., 2010) but fails to define ‘acceptability’. A US trial of sixty-one sexually active women exploring safety and acceptability of VivaGel (McGowan et al., 2011) restricted acceptability to side effects and usage issues of the gel – such as messiness and leakage.

2.4 Conceptualising ‘acceptability’

Many of the studies in the previous section utilised the term ‘acceptability’ in their descriptions of results when exploring how people from HIV at-risk groups perceive PrEP and how they consider its use within the context of their sexual behaviour. However, few provide a clear definition of what they mean by ‘acceptability’, instead using measures including: financial cost to the individual; potential sexual risk

reductions or increases; side effects of PrEP medication; the burden of using PrEP including hospital or clinic visits and procedures – such as regular HIV testing; and the potential stigma and discrimination faced when using a biomedical HIV prevention technology. In general, and across all health behaviours, acceptability is a poorly defined concept. However, clarity on the issue is necessary for a focused exploration of acceptability, as proposed in this current DrPH research.

It is useful to consider the literature on women's reproductive and contraceptive health, particularly with regard to early acceptability studies of contraceptive spermicides and vaginal microbicides. Elias and Coggins remind us that attempting to understand the term 'acceptability' is mired in historical controversy. They note that "once upon a time, the acceptability of contraceptive technology was narrowly defined primarily in terms of method continuation rates" (p3) and that over recent years the term has broadened to encompass user perspectives of a technology and service delivery of new (reproductive) health technologies (Elias and Coggins, 2001).

In Elias and Coggins' exploration of the acceptability of female-controlled barrier methods to prevent heterosexual transmission of HIV, they define acceptability as: "for a product to be acceptable, a potential user must fully understand the potential benefits of using the product, its potential side effects, and alternate methods and be willing and able to consistently apply such knowledge to the use of technology in everyday life" (p3). They state that the provision of information and support, and concerns of cost and availability of any new technology are "implicit in this definition" and that "obviously, the physical and pharmacological characteristics of any given product will directly influence its acceptability" (p3).

Gafos (2013) provides further insight into how acceptability of vaginal HIV microbicides has been framed. She argues that although there has been extensive research into (vaginal) microbicide acceptability, "research to date has focused predominantly on either hypothetical acceptability of a potential microbicide or the acceptability of specific product characteristics" (p 22) and that "acceptability research has focused on willingness to use a product and satisfaction with a particular product" (p22). Socio-cultural issues and conceptual gaps in our understanding of microbicides exist, and that attempts are being made to move "acceptability research ... beyond

purely measuring acceptability of product characteristics, and now attempts to identify and measure the complex set of individual, relational, behavioural and socio-cultural factors that influence the acceptability of microbicides” (p 25).

With most studies exploring acceptability of PrEP alongside efficacy and safety, understanding of acceptability has focused on concepts of usability, adherence and potential side effects, rather than attending to broader sociological or psychological conceptions of acceptability. This is notable given that a risk discourse, explored in detail by sociologists and psychologists alike, appears to pervade thinking about acceptability. This is evident in findings from the Sigma Panel study (Sigma Research, 2011) by the manner in which participants voiced opinions regarding the management of sexual risk, and the Galea et al. (2011) study and concerns regarding sexual disinhibition and risk-taking that may result from utilising PrEP. Consideration of risk(s) might inform many aspects of one’s sexual life, sexual health and engagement with clinical and prevention interventions and, as such, the literature on risk – in particular, on risk and health – helps to further define and interpret the possible elements of acceptability of PrEP for MSM in London.

There are three dominant constructions of risk falling along disciplinary lines: the sociological, the psychological and the socio-cultural.

Sociological concepts and experiences of risk can be broadly divided into three theoretical perspectives. Beck’s theory of the risk society (1992) articulates that, as modern society has moved away from an economy and way of life shaped by industrial processes, today’s “late modern period” has resulted in dangers and hazards that result from industrialisation, urbanisation and globalisation. Beck maintains that an individuals’ life is dominated by anxiety and discussions about risk and the prevention or avoidance of ‘bads’ have become central to the modern world with a reliance on experts to identify and calculate the dangers of those risks (Beck, 1992). Douglas adopts a more anthropological perspective on risk. She argues that concepts of risk are part of shared cultural understandings and practices, forged by social expectations and responsibilities; risk beliefs and behaviours maintain social control and cohesion and are ways of dealing with deviance (Douglas, 1969). Finally, interpretations of Foucault’s governmentality perspective of risk postulates that risk is a tool by which individuals

are self-regulated within society, with individuals voluntarily establishing practices that make us “good citizens” (Castel, 1991, Ewald, 1991). Citizens of modern society avoid risk as a moral enterprise to demonstrate control, knowledge and improvement, with those not willing or able to comply with risk avoidance facing hostility through stigmatisation or moral judgment. This suggests that these elements of control, knowledge and acceptability are ones we might wish to attend to when considering acceptability.

Psychological perspectives of risk are additionally useful in understanding concepts of acceptability in relation to PrEP with MSM. The heuristics or psychometric paradigm approach to risk, developed by Slovic, articulates that ‘expert’ assessments are made of various technological risks that sit alongside ‘lay’ perceptions of their relative chance of the risks impacting upon them (Slovic, 2000). Emotions play a moderating role within risk assessment; with individuals making a judgment on the risk based upon the quality and intensity of negative feelings an individual has about a potential hazard. Finally, Joffe’s social representation approach to risk argues that we should not concentrate on risk approaches that focus on individuals as cognitively deficient or heuristically misguided but rather, explore how individuals explore the meaning of risk through the lens of social forces of moral solidarity and group norms (Joffe, 1999). Joffe understands that ‘managing risk’ does not succeed if it involves devising a correct formula of information but an individual’s perceptions of risk are rather understood as a reflection of their social identification, their moral codes and their trust with and to others.

Men’s perception of risk is determined by social and cultural practice (Beck, 1992; Douglas, 1969) but is also determined by prior experience and meaning. For example, a man’s use of condoms is determined by awareness, by social norms relating to condom use, and his personal risk assessment.

Given the pluralistic nature of public health as a discipline (and given that this is a DrPH thesis), valid and relevant theories across the social sciences are drawn upon. This is a deliberate strategy, to take into account a variety of perspectives, given public health’s wide encompassing embrace of disciplines.

2.5 Developing an acceptability framework

None of these theories or concepts alone is sufficient to understand the meaning of acceptability for MSM considering PrEP in London. However, each contributes to our understanding of the various dimensions of acceptability, and this is furthered still by consideration of existing studies that explored acceptability in its various forms. Sociological perspectives, particularly those drawn from Foucault, suggest that risk is constructed at the social or societal level, and the appropriate, or acceptable, means of managing it help to determine whether we are "good citizens". Psychological perspectives highlight the importance of emotional factors and the personal meanings of risk in determining how individuals consider risk and what risks might be acceptable to take. Given this extant literature, it is proposed to frame an understanding of acceptability building on three broad dimensions of acceptability: the personal; the interpersonal; and the community or social dimensions.

The 'personal' dimension of this framework, will consider the concepts of acceptability that are already primarily explored in existing acceptability studies – the (financial) cost to the individual (incorporating the 'cost' of regular clinic attendance); sides effects and usability acceptability issues (including leakage for topical PrEP or the localised pain of injectable PrEP); the acceptability of potential lowered HIV vulnerability and changes in risk taking behaviour, weighed up alongside potential increases in heightened vulnerability to other STIs; and the acceptability of adherence to PrEP medication regimes and medical procedures. The research has also been designed to be open and responsive to other possible dimensions of personally situated PrEP acceptability, should they arise.

The second dimension moves on from an individual response to PrEP and explores the acceptability of PrEP through inter-personal dimensions. This could be seen to include the more complex negotiation of sex and (non) condom use with sexual partners; issues pertaining to disclosure of PrEP use and how sex might be negotiated with the added dimension of PrEP; the acceptability of risk to sexual partners and/or the risk from sexual partners who might be using PrEP; and the stigma or discrimination faced by PrEP users from sexual partners, from peers or from medical practitioners and health providers.

The third dimension explores acceptability from a community or social dimension. Contemporary commentators on new prevention technologies have included views that biomedical interventions such as PrEP draw resources away from an over-burdened health service, and that condoms are sufficient to prevent HIV infection (Leibowitz et al., 2011; Pink News, 2011), or that health service providers’ attitudes to PrEP may discourage people from seeking it (Boerner, 2014; Kirby and Thornber-Dunwell, 2014). Do such views impact on men’s broader understanding of the acceptability of PrEP and how acceptable are potential increased “community” (rather than individual or inter-personal) risks, such as increased STIs, or more complex (safer) sex negotiations. Finally, this third dimension might explore how rationing or targeting of PrEP is viewed by potential users such as the acceptability of targeting PrEP based on applied epidemiological principles, or being prescribed on demand.

However, it is important not to position the dimensions of this framework as being separate and unique. Rather, each dimension is strongly connected to the other: an individual’s perceived acceptability of PrEP is a consequence of his interaction with others, and of how he experiences and perceives community and societal acceptability of PrEP. Table 1 below summarises *some* of the dimensions of PrEP acceptability that *may* prove pertinent, although this is illustrative and not an exhaustive list.

Table 1: Summary of possible PrEP acceptability dimensions

Personal	Individual financial costs Side effects HIV vulnerability/risk acceptability Adherence to PrEP regime and medical procedures
Inter-personal	Negotiation of sex/disclosure Risk to/from sex partners of PrEP users Stigma or discrimination related to use of PrEP
Social/structural	Financial costs to NHS “Community risk” Rationing/targeting of PrEP Medicalisation of HIV prevention and MSM

2.6 An emerging and fast moving environment

The emergence of evidence and policy on PrEP has been fast moving. At the time that fieldwork for this study was undertaken, evidence on PrEP efficacy existed only from two large international trials and policy on PrEP prescription was patchy and cautious. As outlined above, three clinical trials (iPREX OLE, PROUD and Ipergay) have further added to the evidence on PrEP and MSM, including intermittent oral PrEP, and further Phase II trials on rectal topical PrEP and injectable PrEP are underway.

Further, policy and practice guidelines have moved apace. The US Food and Drug Administration (FDA) issued guidance on PrEP prescription to key at risk groups in 2012 (FDA, 2012); the World Health Organisation (WHO), having been cautious about PrEP in 2012 (WHO, 2012), moved to a robust policy of strongly recommending that MSM consider taking PrEP, alongside condoms (WHO, 2014); and the European Centre for Disease Control (ECDC), after making a policy statement in July 2014 about the need for more evidence on PrEP before making a recommendation (Cairns G, 2014b), shifted position on PrEP, following the release of the PROUD and Ipergay findings (ECDC, 2015). On the basis of new evidence, ECDC recommends member states consider the integration of PrEP into existing HIV prevention programmes, and calls for a review of current regulatory approval of PrEP.

Closer to home, a coalition of non-profit organisations have called for PrEP to be made available on the NHS (PrEP Access, 2014); the British Association of Sexual Health, and British HIV Association, having published guidance in 2012 stating that there was not enough compelling evidence to offer PrEP to patients on demand (McCormack et al., 2012), are consulting on new and more directive guidance on PrEP to its members; and processes are underway to review the evidence base to support PrEP provision on the NHS in England, through the HIV Clinical Reference Group (NHS England, 2015). These developments are highlighted to allow the reader to consider the research design, and its findings, within the current context.

2.7 Chapter Summary

This chapter reviewed the existing evidence relevant to this research and examined contemporary findings relating to three methods of PrEP. Research on acceptability of PrEP has been explored, along with discussion on the challenges of defining what

acceptability might mean. The chapter has outlined how, following a public health approach, multi-disciplinary theories of social science have been drawn upon to understand concepts of acceptability and, as a consequence, a framework for conceptualising PrEP acceptability has been presented, that captures personal, interpersonal and community or societal dimensions of acceptability. Despite recent developments, the fundamental questions posed in this thesis remain the same and remain largely unanswered by research undertaken since completion of fieldwork – how acceptable is PrEP to at risk MSM in London?

Chapter 3: Methodology

This chapter explains the methodology used in this study. First, the research approach is explored, with a justification of why this approach was deemed the most appropriate. The chapter moves on to explore the sampling method and rationale, followed by the ways participants were recruited to the study, using a previous cohort of MSM. This is followed by a description of the key demographics of the men and a detailed account of the research process and a description of the methods of data analysis. The final section of the chapter considers the limitations of the approach, and ethical considerations that were taken into account when designing and undertaking the study.

3.1 Research approach

Given the multiple, discursive elements of acceptability, and the need to understand individual perceptions and considerations relating to PrEP, a qualitative methodology was deemed the most appropriate approach for this study. Although some have sought to understand PrEP acceptability through surveys and other quantitative measures (Frankis et al., 2014), these offer less opportunity to capture the richness of men's thoughts and experiences. Surveys are limited in the extent to which they can account for multiple motivating factors that change in different scenarios or over time. Qualitative research, on the other hand, seeks to capture and preserve the complexities, intricacies and idiosyncrasies of perception, perspective and experience (Buston et al., 1998), which is essential when trying to understand how PrEP might, or might not, be acceptable to MSM and, crucially how interventions might be designed to support its use. One-on-one qualitative interviews provide an opportunity to explore acceptability and allow for the participant to situate their own perspective within broader social constructions of what is, or is not, acceptable. Interviews allow the researcher and participant to engage in meaningful dialogue where initial questions can be modified to meet individual need, and interesting avenues of arising discussion can be explored (Smith and Osborn, 2003).

Consideration was given to a range of qualitative data collection methods other than one-on-one interviews when designing the study. Focus groups were initially proposed and considered as an additional data collection method. Although focus groups have a benefit of accessing cultural norms (Green and Thorogood, 2004), there was a concern

that the dynamics of a group format might silence views of some participants, especially given PrEP as an emerging technology, and considering the sensitivity of the subject area. Diaries were also considered as an option, especially with regard to recording men's sexual risk taking but given the study was aiming to explore co-generation as well as individual views on PrEP, diaries were also rejected as a data collection method. In addition, as diaries are most suitable at examining experience over time – and this is not what I was seeking to achieve – they were further rejected for this reason. While each of these collection methods are valid, it was concluded that a semi-structured interview approach, in contrast to other approaches, would also create opportunities for MSM to bring in themes independently.

3.2 Sampling

In-depth, semi-structured qualitative interviews with twenty MSM were undertaken between September 2012 and January 2013. To be eligible to participate men had to be aged between 18 and 45 and resident in central London, or to have conducted the majority of their recent sexual and social lives in the capital. The study's geographical boundaries were chosen to reflect the enhanced HIV incidence in London compared with the rest of the UK (in 2012, 1,450 of the UK's 3,250 MSM HIV diagnosis were in London MSM (Aghaizu et al., 2013) and the age criteria reflects that the majority of HIV diagnoses – and as such, the likeliest age group to benefit from PrEP – are in adults under 45 (in 2012, the mean age of HIV diagnosis was 34) (Health Protection Agency, 2011). The sample size of twenty men allowed for a considerable range of perspectives to be captured, while still remaining feasible given the confines of a DrPH research project. Twenty is deemed to be a sufficient number of interviews, especially when addressing a specific research question before saturation is reached (Green and Thorogood, 2004). This sample size also allowed for rigorous textual analysis utilising the principles of thematic content analysis (see section 3.7 below).

Qualitative research seeks to understand and describe, in detail, the unique perspectives and experiences of a small number of people, rather than trying to make generalisations about the world. As such, it was not necessary or appropriate to recruit a sample that was representative of all MSM to this study. However, it was still considered beneficial to attend to demographic characteristics to get an indication of whether perspectives on the acceptability of PrEP may differ amongst MSM from sub-populations and whether

such differences could or should be explored in more detail in future studies. As such, I endeavoured to recruit participants from a broad range of ages and ethnic backgrounds.

The original cohort of men from whom this study was drawn included transgender men. To ensure that there was no ambiguity as to whether transgender men were also included in this study, an explicit statement on the inclusion of transgender men was made in the recruitment materials and participation was welcomed from transgender men if they self-identified as a man who has sex with other men and they met the other eligibility criteria.

In order that they were eligible to take part, men had to have received a negative HIV test result in the last 12 months prior to interview recruitment and have had at least one episode of known sero-discordant sex without condoms (SWC) or SWC with a partner whose HIV status was unknown or not discussed in the same period. An explicit definition of ‘anal intercourse’ was given in the recruitment material, which defined anal intercourse as penile to anal intercourse and excluded non-penile penetration such as dildos, sex toys, fists, and tongues. These eligibility criteria reflect a definite at-risk group who would be most likely to benefit from PrEP related interventions, given that penile anal intercourse is known to be the route by which most HIV transmission occurs during sex between men.

3.3 Recruitment

Respondents for the study were recruited through a mailing list of Sigma Research, a social research group based at the London School of Hygiene and Tropical Medicine with a history of undertaking HIV related research with MSM. Men on the mailing list were part of a previous cohort of MSM participating in monthly online sex and health surveys called ‘The Sigma Panel’, that ended in 2011, who had indicated they were willing to be contacted to take part in future research. In section 3.3.2 below, a description is given of how men were recruited to this panel and then goes on to describe how I sampled from among this group of men in the panel for my study.

3.3.1 Recruiting to the Sigma Panel

Men were recruited to this previous cohort by a variety of paid advertising on gay commercial websites (such as www.gaydar.com) and gay community or HIV

prevention organisations. Men living in England who had completed a European internet survey of MSM (EMIS) had been asked if they wished to provide an email address and be contacted to take part in future research. These men were emailed and invited to be part of The Sigma Panel. Of the 3,390 men who provided an email address and who were invited to take part in The Sigma Panel, 1,823 submitted a response to the first survey. Of these men, the mean age was 42.4 years; 35% lived in London; 82.6% were attracted to men only; almost half had a higher educational qualification; 82% were White British, 12.9% White other, 1.6% were Black; 2.4% were Asian, and 1.3% defined their ethnicity as Other.

The 1,463 men who submitted a response to the final survey in February 2011 were asked if they were prepared to provide an email address to be contacted for future research and approximately 1,200 men responded to this request. It is these men who were contacted by email and were invited to participate in *this* PrEP acceptability study.

3.3.2 Recruiting to the PrEP acceptability study from the Sigma Panel

An email was compiled that stipulated the eligibility criteria for the study and that the study was seeking to explore men's views on 'using HIV medication to prevent HIV' (Appendix 1). The email invited eligible men to participate in the study by visiting a secure Survey Monkey site (www.surveymonkey.com/prepaceptability) in order to complete a short questionnaire (Appendix 2).

The list of men from the Sigma Panel that was shared with me for the purposes of recruitment contained only email addresses and no demographic information (such as geographical location, age, HIV status, HIV testing history nor sexual activity). As such, the majority of men approached by email were not eligible to participate, as they did not meet the criteria for the study (for example, they lived outside of London and/or had been diagnosed with HIV). Men who were not eligible to participate who raised questions or concerns about their non-eligibility were responded to individually by email and provided with further details about the study and clarification of the reasons for the eligibility criteria.

One third of the panel mailing list was emailed at the start of the study and non-responders were followed up with a reminder email several weeks later. No further

follow up was undertaken after this. Two further rounds of emails were sent out in October 2012 and then in December 2012 for the remaining two-thirds of addresses on the list, each followed up with reminder emails to non-responders several weeks later. In the final round of email recruitment, emphasis was placed on the desire to recruit men under 30 and non-white men in to the study, without discouraging other eligible participants.

Men who visited the Survey Monkey web site were furnished with further information about the study and were reminded again of the eligibility criteria. The website reassured men that their details would remain confidential, that their ISP data would not be stored, and that the website was provided by a secure provider. Men were asked to complete a series of demographic questions to re-check their eligibility to participate and a number of questions relating to their HIV status, recent HIV testing history and episodes of unprotected anal intercourse in the previous 12 months. When men's responses to any question indicated they were not suitable for participation, they were automatically directed to an end page thanking them for their interest in the study but informing them that they were not eligible to take part. Men who fully completed the survey, and who fully met the eligibility criteria, were invited to supply a contact name (a first name only) and a telephone number and/or an email address. Men were asked for consent again to be contacted by their chosen method and for permission for a voice mail message to be left, if a telephone number had been given.

In the first recruitment round, all men who met the eligibility criteria, who provided contact details and who responded to interview requests were offered the opportunity to participate in a face to face in-depth interview. In the second and third rounds of interviews, three men were assigned to a 'reserve list' and were not followed up for interview. These men were older, of white ethnicity and possessed higher educational qualification: characteristics that were common in those men who had already been interviewed.

Upon expressing an interest in participating in a face-to-face interview, men were provided with further information about the study and the interview process. This was provided either verbally through a telephone conversation or through an email. All men were informed that the interview was voluntary, that it was confidential, and that it

could take place at a date, time and venue of their choice, including at the participant's home or in an office at LSHTM. When email details were provided, participants were furnished with a copy of the Information Sheet (Appendix 3) and Consent Form (Appendix 4) in advance, and paper copies of these were provided at the interview.

In addition to the recruitment processes detailed above, one participant – the first – was recruited through my own social networks (but was previously unknown to me). This participant understood that his use of the Survey Monkey website was being seen as a pilot, to test the functionality and understanding of the web survey and that his interview was being used to pilot the interview topic guide. Given that no changes were made to the Survey Monkey website and so few changes were made to the interview schedule following this pilot, it was deemed that the pilot data was of suitable quality to include in the study. Post interview he gave full consent for his interview data to be included in the study.

3.4 Sample description

All participants had had a negative HIV test in the previous twelve months prior to interview and all men had had at least one instance of SWC with a known HIV positive partner, or a partner whose HIV status was unknown or not discussed, since that last HIV test. Seven of the men knew for certain that they had had unprotected anal intercourse with a known HIV positive partner, and five of the men were in primary relationships with HIV positive partners, although the sero-discordant SWC that determined their eligibility for the study was not necessarily within those primary partnerships.

There was a wide variation in educational attainment. Two of the men identified their ethnicity as being Mixed and one as Black. Men's ages ranged from 21 to 45, with a mean age of 34. One of the participants identified as a transgender man. The participant names included in the following table, and throughout the report, are pseudonyms.

Table 2 *Age, ethnicity, and education of sample*

Name	Age range	Ethnicity	Education	Known s/d SWC
Simon	25 + under	White British	Degree	No
Ed	25 + under	White British	To 16	No
Max	26-30	Black	Degree	No
Jos	26-30	White British	To 16	No
Philip	31-35	White British	Degree	Yes
Louis	31-35	White British	To 18	No
Mattie	31-35	White British	Degree	Yes
Marco	31-35	White Other	Degree	No
Yan	31-35	White Other	Degree	No
Alex	36-40	White British	Degree	No
Brad	36-40	White Other	Degree	Yes
Javi	36-40	Mixed	Degree	No
Duncan	36-40	White British	Degree	No
Francis	36-40	White British	Degree	No
Martin	36-40	Mixed	Degree	Yes
Colin	41-45	White British	Degree	No
Roy	41-45	White British	Degree	Yes
Nate	41-45	White Other	Degree	No
Jovan	41-45	White Other	Degree	Yes
Marc	41-45	White British	Degree	Yes

(Note that in the table above, in the final column, ‘No’ relates to men who had SWC with a partner where sero-status was unknown or not discussed.)

3.5 The research process

Prior to commencement of interview, participants were again provided with an information sheet about the study (Appendix 3). This information sheet outlined: the nature of the study; the ways in which participants would be involved, including that the interview would be audio recorded; how a participant’s information and details would be kept confidential, including systems for storing, access to, and destroying audio recordings and transcriptions; and that participants could withdraw from the interview at any time, or ask for the interview to be stopped without giving a reason. Participants

were given the opportunity to discuss any elements of the information on the sheet and the processes around confidentiality were verbally reiterated (see section 3.9).

Participants were reminded that the interview was not a test of their knowledge and that they should be as candid as they felt comfortable to be.

Before interviews started I re-confirmed to participants the nature of my role as a researcher and described that I had previous experience in sexual health related social research. I reassured men that my previous research and professional experience meant that I was used to hearing about a broad range of social and sexual issues pertaining to MSM, and invited them to be as candid as they wanted to be, and as open as they felt comfortable being. Cornwall's (1984) research on the contrasting 'public' accounts given by interviewees at first interview, compared with the 'private' accounts given during follow-up interviews, demonstrates how less 'deviant' and more 'socially acceptable' accounts are given when a participant sees the interviewer more as a researcher rather than a confidante. Given I only interviewed men once, and did not have the chance to build an on-going relationship with participants, and based upon previous research interview experience, I made a decision to disclose my own (homo) sexuality at the start of the interview. As well as establishing a rapport, I wanted men to understand my role as a 'peer' rather than a 'medical professional' and to encourage open discussion. Participants were comfortable with this disclosure and, in some instances, remarked during interviews that they would not have disclosed certain information had I not done so.

Once participants had read the information sheet and had the opportunity to ask any questions, they were asked to read, sign and date a consent form (Appendix 4) and participants were verbally asked if they had any further questions before proceeding. All interviews were audio recorded.

3.6 Interview schedule

This section starts by describing the process of interview schedule development. This is followed by a description of the questions that were asked of men and the reasoning behind various aspects of the schedule.

3.6.1 Developing an interview schedule

Guided by the dimensions of acceptability that were identified earlier, as well as prior research on PrEP acceptability, I drafted a schedule of interview questions to address the research objectives. These questions were also framed by representations of PrEP in the mainstream media and in the gay and MSM targeted media, including social media, web sites and blogs particularly in regard to exploring the third social/structural dimensions of acceptability including ‘community’ (Evans and van Gorder, 2014; Glazek, 2013; Stern, 2014a) responses to PrEP that participants may have encountered or been exposed to. Questions were open-ended to allow for broad articulation of acceptability by participants. Appropriate prompts and probes were devised to be used where natural dialogue was not forthcoming. The schedule of questions was reviewed and discussed, prior to interview, by members of the advisory committee and were informally piloted on a research degree student colleague. A pilot interview schedule was used with the first interviewee and the questions were found to be understandable, acceptable and appropriate. The same interview schedule was used for a further four interviews before being reviewed again. At this stage, I transcribed all five interviews and transcriptions were discussed with my supervisor. No further changes were made to the interview schedule (Appendix 5). However, three ‘prompt cards’ were devised and used for the remaining fifteen interviews. These cards contained bulleted key highlights of three research trials and were used during interviews to prompt discussion on attitudes to and acceptability of different PrEP formulations (Appendix 6). These cards were devised to ensure that interviewees were being exposed to consistent and concise information on these trials and to ensure that no elements of the trials were omitted or incorrectly articulated.

3.6.2 How men meet for sex

At the start of the interview men were asked to describe how and where they socialise with other men. The question was intended to introduce men gently into mechanisms for describing where they meet other men for sex and to encourage them to start describing their sexual networks, sexual relationships (including if they have a regular partner, are monogamous etc.) and their sexual practices. Men were prompted to describe the settings in which they socialise and/or meet other men for sex (including bars, clubs, sex venues, saunas, cruising grounds); their use of social media, social and sexual networking sites for meeting men; and their use of media technologies such as

mobile phones to meet other men. In addition, men were prompted to describe the extent to which they pre-planned their sex and/or the extent they looked for immediate or imminent sex.

3.6.3 History of HIV testing and sexual risk behaviour

Men were asked about their more recent HIV testing history and were asked to describe the circumstances behind their most recent test and the reasons for that test. Men were asked if they had a rationale or a pattern to their HIV testing – for example if they tested at regular frequency, regardless of previous sexual activity or risk, or if their testing was more ad hoc, or dependent on a recent risk. Given that an eligibility criteria was that all men had had SWC since their most recent test, and within the last 12 months, men were asked to describe the SWC they had had since their last test. The circumstances behind that sex were explored, including whether it was with a regular or casual partner; whether it was known discordant intercourse; whether the unprotected sex was discussed before or pre-planned or ‘just happened’; and if HIV status was discussed before or after sex. Men were asked to describe any other unprotected intercourse they have had, including the frequency of it, whom it had happened with, and the circumstances behind that sex.

If not already discussed, participants were asked if and how they have managed or thought about managing HIV risk during condomless sex. They were prompted to discuss modality, withdrawal, frequency and duration of unprotected intercourse; and if a known HIV positive partner was on treatments and had a known and undetectable viral load.

3.6.4 Use of PEP

Given that previous use of existing oral HIV prevention technologies might influence acceptability of PrEP in the future, men’s use of post exposure prophylaxis (PEP) was explored with men, and men were prompted to discuss their knowledge, use or experience of PEP to reduce HIV risk. Men were asked to describe what they knew about PEP and the sources of that information. They were asked if they had ever attempted to access PEP and, if not, what had been the barriers to accessing this post exposure medication. Men who had attempted to access PEP, and had taken it, were asked to describe their experience on PEP, and whether they had completed their

treatment and what had been barriers and impediments, or mechanisms of support, to completing the treatment.

3.6.5 Knowledge of PrEP

Participants were reminded that the purpose of the research was to explore views about the acceptability of using HIV drugs to prevent HIV infection in men who do not have HIV. They were told, if they had not already articulated such, that the drugs are commonly called pre-exposure prophylaxis or PrEP. Men were then asked if they had heard about PrEP, and to describe what they had heard about it. If men articulated knowledge of PrEP, they were asked about the source of that knowledge, and to say if they had used PrEP or had sought access to PrEP.

3.6.6 Potential oral daily PrEP use

All participants were furnished with the key headlines of the iPREX trial, which reported in 2010. The trial design was briefly explained and the headline results of the trial. It was clarified that adherence to Truvada, in the trial arm, had been key to its efficacy. It was confirmed that there had been no short-term side effects to trial participants.

Men were given the opportunity to discuss any questions they had about the top-level trial findings and were then asked to describe their responses to the results of the iPREX trial. Respondents were asked to recall if the results of the iPREX trial were familiar to them and where they had learnt about those results.

Participants were also asked, if daily oral PrEP became widely available, would they consider taking it. Men were then asked about the kinds of issues they would consider in making that choice to take, or to not take, a daily oral dose of Truvada and in what circumstances they might consider taking it.

3.6.7 Potential other PrEP method use

Men were then told about four other possible formulations of PrEP that are either in trial development, in consideration or exploration, or have been explored in ‘pipeline’ development. For each, relevant available research data was presented to the participants where this was available.

For each method, men were then asked to describe their responses to the information on the prompt cards; to articulate if they would consider using such a formulation, should it become available in the UK; what issues they would consider before making a choice to take, or not take that formulation; and to articulate the pros and cons of that formulation methods over any of the other methods described. If this was not mentioned, men were prompted to discuss the impact of PrEP on their condom use and if and how PrEP might sit alongside their current risk reduction approaches.

The four methods discussed were:

Intermittent dosing of oral PrEP before pre-planned or pre-expected unprotected sex. It was noted that no current research findings were available on using PrEP in this format but that a current French study was exploring the use of intermittent dosing (Molina et al., 2015).

Rectal topical PrEP. The key headlines from the CAPRISA trial (Abdool Karim and Abdool Karim, 2010) were presented to men on a ‘prompt card’ and participants were informed that the use of topical rectal PrEP was being explored in a number of safety trials and efficacy trials (Microbicide Trial Network, 2015). Men were informed that although women in the CAPRISA trial had inserted the gel vaginally no more than 12 hours prior to intercourse, and no more than 12 hours after intercourse and that it was still unclear what the optimal pre and post insertion timings might be for such a gel.

Once a month injectable PrEP. Men were presented with the key headlines of a safety trial from St Stephen’s Aids Trust (Jackson, 2012) on a ‘prompt card’ and were informed that these were the results of a safety trial only and that further research needed to be conducted.

Longer term injectable PrEP. Men were asked to consider a concept of a longer- term injectable or implanted formulation of PrEP, similar to long-term contraceptive methods. Men were informed that no such method currently exists, although it has been discussed in the ‘pipeline’ as a potential slow release method of PrEP administration (Andrew et al., 2013).

Men were given the opportunity to clarify questions about any of the methods discussed.

3.6.8 Inter-personal acceptability of PrEP

Once all potential methods had been presented and discussed, and having gauged a broad sense of individual men's responses to PrEP, participants were asked about inter-personal dimensions of PrEP. First, men were asked to describe the response of their social peers to PrEP and to explore if men they know might consider using PrEP, and in what circumstances. Men were also asked to describe if they would disclose their own PrEP use to men in their peer group, and if they had a perception that PrEP use would hold any element of stigma, discrimination or taboo amongst their social peers.

Second, men were asked to consider their potential PrEP use in relation to their sexual partners (who might also be their peers, above). Participants were asked if they thought they would disclose PrEP use to sexual partners and to consider if and how their potential PrEP use might impact upon negotiating the kind of sex they have with other men. Again, they were asked if PrEP use might hold any element of stigma, discrimination or taboo amongst their sexual peers.

Third, participants were asked to think about their own sexual negotiation if they encountered another man using PrEP, when the participant was not using PrEP. Would knowing another man was on PrEP make a difference?

3.6.9 Societal and community acceptability

As a final stage participants were asked to consider wider societal responses to such an intervention. Apart from their social and sexual peers, men were asked if they had perceptions of how PrEP might be viewed by a broader community of MSM, outside of their direct peers and by the media, health professionals or 'wider society' and if any of these perceptions might impact on the man's decision to access PrEP.

To bring the interview to a close, men were asked to summarise what would make PrEP acceptable to them, and were given an opportunity to reflect on the discussions during the interview.

Post interview, participants were provided with an information sheet about PrEP (Appendix 7) and provided with the opportunity to address any of the information discussed during the interview. This is discussed further in section 3.9 on ethical considerations.

My email details were provided, so that participants could opt in to receiving a summary of the final research.

3.7 Data analysis

There are numerous available methods of qualitative data analysis, which differ according to the assumptions they make about the nature of the world and what can be inferred from spoken language, but all seek to understand subjective perspective or experience, as well as meaning. For the purposes of this research study, I drew upon the principles of thematic analysis (Boyatzis, 1998) to understand the acceptability of PrEP amongst MSM. Thematic analysis provides a comparative process by which the content of the interviews are compared and classified in to recurrent themes. Braun and Clarke (2006) make a compelling case for drawing on thematic analysis in qualitative (health) research – arguing that its flexibility and accessibility also provides richness and complex accounts of data. Thematic analysis acknowledges the importance of both individual lived experience (‘the psychological’) and the nature of social processes (‘the sociological’). This stands in contrast to largely discipline specific analysis such as Interpretive Phenomenological Analysis (IPA) (i.e. psychology) (Smith, 2003) or Grounded Theory (i.e. sociological) (Charmaz, 2006; Glaser & Strauss, 1987). In seeking to understand the acceptability of PrEP it is crucial to understand both how participants respond to risk in the context of their sex lives and how they negotiate this with sexual partners in inherently social interactions.

Further, Braun and Clarke (2006) highlight the strength of undertaking thematic analysis when research is being conducted that will be accessible to an audience other than academics. Such an analysis, drawing on subjective experience and thematising it through the process outlined below, humanises the material for the reader. Such a choice is further relevant and when producing analysis that aims to inform policy

development, making thematic analysis suitable for a DrPH thesis. Analysis of data broadly followed Braun and Clarke's phases of thematic analysis, as outlined below.

All interviews were audio-recorded and fully transcribed verbatim by myself. This included pauses, interruptions, laughter and other background noise. Any identifying information such as real names, place names and venue names were removed during transcription. Interviews lasted between 40 and 70 minutes. Self-transcription of the data, although time consuming, allowed for a far richer knowledge and understanding of the data (Riessman, 1993) and constituted part of the interpretation and analysis of the data itself (Lapadat and Lindsay, 1999).

NVIVO7 was used as an analysis tool for the data. Each participant was assigned to a case, with attribute data for the case coded as a case node (Bazeley, 2007) including key demographics such as age, ethnicity and educational qualification. An initial coding scheme was developed following transcription of the first five interviews with initial tree nodes created. These nodes were both inductive and deductive: my own prior professional practice and reading of the PrEP literature ensured I was attentive to certain issues that I wanted to examine in more detail, however I remained entirely open to the possibility of new and interesting issues emerging (which indeed they did). In order to ensure complex and divergent data was not lost in the process of establishing the coding tree, a number of free nodes were created and used during this initial analysis for data that did not initially sit within the tree nodes. These tree nodes included men's accounts of SWC; delivery method of PrEP – with each of the five potential methods as branch nodes; and risk reduction strategies. These themes were discussed with my supervisor and then verified with him following further transcriptions of interviews. These themes were discussed further with support of the advisory committee, and a framework was constructed to illustrate their connectivity.

As the further fifteen interviews were coded, a small number of additional tree modes were created, and data from free nodes were merged into these. On completion of coding, each tree node was thematically analysed. Each node (and/or its branch) was printed and analysed for recurrent and common themes (Green and Thorogood, 2004). Interesting features, including justifications, narratives and metaphors were highlighted and interrogated for meaning. As suggested by Braun & Clarke (2006), at the

fundamental level, a theme represents a form of patterned response or meaning within the dataset. While not seeking to establish an arbitrary cut off for how often such a pattern emerges in the data before considering it a theme, I was carefully attentive to whether such patterns were replicated across transcripts or whether they emerged only within specific cases. As far as space allowed within this thesis, I tried to take account of variation as well as partial duplication in narrative and meaning expressed by participants.

At this point a decision was made to include four case studies as part of the study's results (Chapter 7). This decision hinged on two key factors. The first, given the process of deconstruction and reconstruction employed in thematic analysis, I wanted to present a more 'holistic' understanding of four different participant's understanding and views on PrEP, not least to identify and illustrate the individual complexities and contradictions about PrEP acceptability. Second, given the applied nature of this research, I wanted to present over-arching narratives for non-academic readers that summarised four key 'stories' (but by no means all of the stories) pertaining to PrEP acceptability in a way that neatly captured the essence of the findings.

These four men were selected as case studies as they provided the most distinct characterisations of PrEP acceptability and potential use: the naïve risk taker, for whom PrEP would not be deemed acceptable as the man could not recognise his HIV risk; the man who definitely would seek PrEP; the ambivalent man, for whom PrEP would be acceptable in certain circumstances but had a considered approach to determining PrEP use; and the man who would not use PrEP, broadly for whom HIV risk was deemed insufficient to warrant PrEP.

3.8 Quality, rigour and reflexivity

Qualitative research acknowledges that we bring something of ourselves and our beliefs into the research process, and that this necessitates a level of reflexivity and awareness of oneself within the process. Such reflexivity enhances the quality and credibility of the analysis (Green and Thorogood, 2004) and contributes to the rigour of the research. Guidelines exist for assessing and checking quality in quantitative research, such as those developed by Elliot et al (1999), including the extent to which one's own perspective is owned.

Green and Thorogood establish four considerations to inform reflexivity, each of which informed my own research practice (and in turn the credibility and rigour of the research and the analysis): methodological openness (as outlined throughout Chapter 3); theoretical openness (as outlined in particular in section 3.7); awareness of the social setting of the research itself (which is, in part, discussed in section 3.9); and awareness of the wider social context (which is addressed and acknowledged throughout, not least in the Discussion and Conclusion chapters). My own subjective position within the research is further addressed in Section 3.11 below.

3.9 Limitations of the study

As with all research, there are a number of limitations with this study design of which the reader should be mindful of when considering the findings that follow.

As outlined, participants were drawn from a cohort of men who had previously engaged in online sexual health research via the Sigma Panel. As such, participants of my study were likely to be drawn from groups of men who are more amenable to research participation. Men who signed up to participate in the original online research (from which my study participants were recruited), who then did **not** go on to participate in that research, were more likely to be less well educated, from a Black or minority ethnic group, and to be younger, than those men who participated in the research. Those same demographic groups of men were also more likely not to respond to a request for interview, or agree to be interviewed, for my study, meaning that the final group of study participants were more likely to have higher educational qualifications, to be older, and to be more likely to be White (both White British and White Other). As such, the study reflects the views of men who are more likely to be socially or economically privileged and their perspectives may differ from other sub-populations of MSM.

In addition, given that the cohort had previously been asked questions relating to PrEP in a survey, in June 2011, some men would have been exposed to information pertaining to PrEP by participating in that survey. Not all men will have responded to the invitation to participate in that survey's PrEP questions, nor necessarily opened the email inviting them to participate in those questions. As such, a potential limitation could be that men recruited to the study were already well versed about PrEP, with

PrEP knowledge, awareness and consideration well beyond that of most MSM. However, few of the participants identified that survey as their source of PrEP knowledge and those who did rarely had a robust knowledge and understanding of PrEP. Additionally, the research was not seeking to establish participant's knowledge of PrEP, rather their attitudes about it and potential acceptability of PrEP. As such, although it might be the case that these men might have been better informed about PrEP than would otherwise have been the case, this is not seen as a limitation of this study.

Taking these potential limitations into consideration, caution should be given into the transferability of the findings of this study to less-educated, more ethnically diverse, and younger populations of MSM. Further consideration of the limitations should be given when considering transferability outside of London, or other high HIV incidence and prevalence populations. Previous research has documented how a greater proximity to HIV (with regard to local prevalence and familiarity with those living with HIV) can influence and inform both a perception of personal risk and the strategies employed to manage it (Keogh, 2008).

Finally, at the time of the commencement of the fieldwork, oral daily PrEP was not available in the UK, other than through self-importation from abroad. Although recruitment to the clinical PROUD trial (McCormack et al., 2012) started towards the end of the fieldwork, none of the participants had enrolled on that clinical trial at the point of interview. With the exception of the one participant who was buying PrEP himself online, none of the participants were using PrEP, and indeed PrEP knowledge was new to many men. As such, participants were being asked **hypothetical** questions about **potential** PrEP use for technologies available only in clinical trials or technologies in pipeline or concept development. A limitation of this study could be that the hypothetical nature of the potential PrEP use limits the depth and breadth of men's knowledge of and desires to engage with acceptability of technologies that are not currently available. However, a benefit of undertaking field work prior to the commencement of enrolment to a large clinical trial is that it established acceptability to an HIV prevention technology prior to its wider implementation. Indeed, undertaking research about PrEP technologies when **all** of the technologies are unavailable gives a level of consistency to men's consideration of their potential use (rather than comparing

in-use technologies with pipeline ones). Also, and as discussed, consideration of an intervention's acceptability *prior* to its roll out can be seen as crucial to ensuring it meets the needs of the target population and scientific and clinical potential is realised in the real-world.

3.10 Ethical considerations

Ethical approval for the study was received from the Ethics Committee at LSHTM.

As a prospective and theoretical exploration of a potential new technology, it was not envisaged that there were any significant ethical issues relating to this proposed research. However, given the research was asking participants about their sex lives and their potential exposure to HIV there was the potential that participation in the research might raise concerns.

To mitigate against any potential harm from participation, a number of safeguards were put in place. These included: ensuring that men were appraised in advance of the interview about the issues that would be discussed; that informed consent to participate was obtained (including that men could withdraw at any time); and that a post-interview information sheet (Appendix 7) was provided and discussed with every participant post interview. This sheet contained: a lay-person's summary of currently available information about PrEP; reiterated that PrEP is different from PEP – and provided information on where to access PEP; stated the importance of not sharing another person's HIV medication; and reminded participants that PrEP does not protect against other sexually transmitted infection. The sheet included contact numbers of sexual health specialist services for men who had any further questions regarding the management of sexual risk and participants were made aware of, and sign posted to, appropriate information or services after the interview was complete, if and when necessary. Men were given the opportunity to discuss any further questions regarding PrEP prior to leaving.

My previous experience as a sexual health promoter ensured that I was equipped to provide referrals and information to men post-interview and provide the opportunity for participants to check-out factual information about PrEP, HIV prevention and sexual health. I was also equipped with referral details of specialist sexual health counselling and psychosexual health services should men require the need of such services as a

result of issues raised during interview, although referrals were neither required nor requested as no participant expressed or demonstrated concerns about their emotional well-being during interviews.

Considering that men were discussing and disclosing intimate and personal aspects of their (sex) lives, men were provided with additional reassurance around confidentiality. This included considerations around where interviews took place (interviews were conducted in places where men could not be overheard – often their homes); storage of audio files and documentation (all audio files were uploaded to password protected files and audio recordings were deleted after being transcribed); and how transcribing would be undertaken (by me), and how data would be anonymised (with all real names and geographical locations deleted and names replaced with pseudonyms).

Given my previous career as a sexual health promoter, including some high-profile work, there was potential that I had previously interacted with participants on a professional basis. As a gay man frequenting social and online settings within the capital, and with a broad social network, there was also the potential that participants, or those interested in the study, would be known to me directly, or be directly connected with my professional or social networks. On the very few occasions when this occurred and was identified (either by me or by a potential participant), the participant was given the opportunity to withdraw. When interviews proceeded, additional reassurances regarding confidentiality and anonymity were provided.

[3.11 My subjective position within the thesis](#)

Throughout the process of undertaking this thesis, I have been cognisant of my subjective position within it, as a gay (queer) man; as someone with a former career as an HIV health promoter; and as an HIV prevention activist. While I make reference to both my former career (in the Integrating Statement) and my sexual orientation (in respect to the ethical approach I undertook), further consideration of my position, and the influence of that position on the research is worthy of acknowledgement and discussion.

Given that background, my research area and my desire to produce research that influences policy and inspires change is inevitable. Despite Green and Thorogood's

(2004) categorisation of such a research approach as being that of “the radical”, I started this research being broadly skeptical of bio-medical approaches to HIV prevention, even when they are so entwined with behavioural approaches. As long ago as 2003 I was “broadly supportive” of more research into PrEP (Allen, 2003) but held a healthy scepticism about PrEP long into the research process of this thesis. Indeed, undertaking this research heavily influenced my policy and practice analysis: scrutinising international research and talking in-depth to MSM about the potential for PrEP radically shaped my HIV prevention activism, rather than that activism shaping the research.

3.12 Summary

This research study explored the acceptability of PrEP with MSM in London. A qualitative approach using semi-structured in-depth interviews was used, with interviews being conducted with 20 MSM. Men were recruited from an existing cohort of men who had previously participated in online sexual health research. The methodology was appropriate for the study as it allowed exploration of PrEP acceptability and potential future PrEP use with a view to guiding development of policy and practice for PrEP awareness and prescription, in relation to other HIV prevention strategies and policies.

Chapter 4: Results - How men manage their sex lives

In this first results chapter I address the ways in which men in the study described the management of their sex lives. The places where men meet for sex, and how men encounter sex, are important factors in establishing the circumstances in which PrEP might be acceptable, or not, as well as where PrEP education might meaningfully be delivered. Understanding men's account and narratives of the circumstances in which, and why, they have sex with and without condoms assists in contextualising men's PrEP acceptability. Finally, men's decisions relating to HIV prevention is unlikely to be singular (i.e. it will not be PrEP verses no prevention at all) and, as such, it is important to understand the context and value that other risk-reduction strategies hold for men. This first chapter is essential in contextualizing narratives of how men 'do' sex and how they manage risk in the current absence of routine access to PrEP.

4.1 Settings where men encounter sex and planning for sex

Research on MSM provides compelling evidence that the settings in which men meet for sex, or where men encounter sex, has changed over the past decade and a half (EMIS, 2013; Frankis and Flowers, 2005; Frankis and Flowers, 2009; Keogh and Weatherburn, 2000; Weatherburn et al., 2003). As is explored subsequently, whether men pre-plan their sex, or instead encounter sex more spontaneously, has implications for the relative acceptability of different PrEP methods. As such, it is important to understand how men in this study plan for and encounter sexual partners.

Given that men were recruited to the original Sigma Research cohort online (from which this study recruited), and in some instances, through recruitment adverts in online gay chat and sex sites, it is not surprising that the majority of men reported using the internet to find sexual partners. While a small number of men reported that their primary means of securing sex was through sex on premises venues (such as saunas or sex clubs that are favoured by some MSM for the immediacy of sexual contact that they facilitate), and fewer still used cruising grounds or public spaces to engage in sex with other men, almost all of these men *also* used the internet as a way of finding sex. Only Jovan indicated that he preferred what he termed a more 'old fashioned' way of finding sex.

“That’s it! I pick up men in the old fashioned way! It’s so easy. Give someone the eye. Give them a double take. I am very direct and I go up to them and say, ‘Hey! Let’s get naked and fuck!’ or something of that nature”. (Jovan)

Using the commercial gay scene (i.e. clubs and bars) for meeting men was far less common than using the internet and participants over 40, in particular, reported that their patterns of setting use had changed in recent years, with a decline in the use of the commercial scene. Issues around ageing, including the inability to converse in settings with loud music, contributed to older men’s reduced use of bars, whilst other factors included: the cost of going out; the dislike of being around men under the influence of drink or drugs; discomfort with being associated with (other) gay men; and, in the case of migrant men, a feeling of not being welcome. For one such man, the struggle of understanding the ‘codes’ of communication and cruising in bars had turned him off the commercial scene.

“When I moved to England I found it very, very disturbing because no-one was coming to talk to me and I thought, ‘what is wrong with me?’ because I’m [a] very free guy, fairly attractive and suddenly no-one talk to me. I was like, ‘Urgh! What happened?’ ” (Marco)

Broadly, clubs and bars (rather than sex venues) were viewed as settings in which to socialise, where men would meet with friends, rather than a place to ‘pull’. If sex happened, it tended to be opportunistic, rather than a man having an intention to ‘go out on the pull’. In some instances sexual encounters in bars and clubs would be facilitated using smart phone apps.

The fifth of men who did not currently use, or no longer used, the internet for sex were put off by experiences of men who misrepresented themselves online or did not follow-through with meeting up or the inordinate amount of time spent chatting and swapping photos only for the encounter to be postponed. For others, there was a concern about meeting someone they had never met before, either from a safety perspective or because they were not comfortable with having sex with strangers. However, most men’s narratives concerned the *opportunities* that the internet provided; enabling some men to facilitate sex with others without having to mix with other gay men, or because they felt they did not ‘fit in’ with the gay scene, or because they found the gay scene unsavoury.

For a quarter of participants the internet offered a sense of flexibility or convenience, when work, travel or other commitments ruled out the chance of using clubs or bars. However, the biggest opportunity of the internet was the immediacy of encounters and the ability to be spontaneous: men did not have to wait until a bar opened if they were feeling sexually aroused but could log online.

“It’s a lot easier to go online and have someone over within 15, 20 minutes, rather than spending 2 hours looking at someone out the corner of your eye!”
(Martin)

Smart phones have further enhanced this sense of immediacy, allowing men to secure sexual partners while in motion, travelling around the city, or simply in quiet periods throughout the day. Operating through ‘apps’, smart phones allow for users to create a profile, often with photographs, that describe the user’s sexual preferences and the activities they are seeking. Most are geo-specific, allowing users to connect with others in their immediate geographical vicinity. For Alex, a smart phone meant that he no longer sat in front of his computer *‘for hours. And hours. And hours’* as he could pick up men as he travelled around, using his phone. For Javi, being able to encounter men passing through his neighborhood, meant he no longer had to deal with the ‘time wasters’ who would chat online for hours, and then say it was too far to travel to meet.

“They tend to happen more on the street, literally on the corner and we say ‘come over’ and he says ‘yes’ and then he comes over. That is the way that most of that happens”. (Javi)

The majority of men who used the internet to meet men for sex used it for immediate sex, driven by the convenience and immediacy, rather than to facilitate pre-planned sex in the future: to meet a need now rather than to fulfill a future need.

“I was in my hotel room last night and somebody was 3 floors down and it was, ‘am I coming to your room or are you coming to mine?’ and it’s ur ... it’s that easy!” (Colin)

When men did use the internet for planning sex ahead, they were more likely to do so with men who they had already established a connection with – that is, men they knew

or who they had previously hooked up with and who they trusted to follow-through on their agreement to meet for sex.

In summary, this data confirm the findings of contemporary research amongst MSM on the use of settings to meet men for sex: that increasingly men find their sexual partners online, and men see that this as an opportunity. Along with this, many men's sex is spontaneous rather than planned and, when it is planned, is frequently with men they have previously met or encountered. GPS based phone apps facilitate this spontaneous sex, allowing men to have unplanned encounters more frequently. As will be explored in the following chapters, the ability to increasingly have unplanned sex had implications for how acceptable men considered PrEP to be, and how this judgment varied according to the method of PrEP delivery.

4.2 HIV Testing: frequency and rationales

Having considered how men plan for and encounter sex, and the potential implications for PrEP acceptability, this section considers the role that HIV testing plays in men's risk analysis. Not only did participants use HIV testing to inform future decisions about sex, but more often men use testing to reassure themselves of their HIV status following a particular sexual activity or risk period. Understanding how men test and their rationales for testing, are important considerations in PrEP acceptability: not least given the necessity of regular testing in PrEP regimes.

Almost all the men had an established routine of testing, influenced by either number of partners, the type or amount of sex they had had since their last test, the duration of time since their last test, or a combination of these. A small number of men used birthdays, anniversaries or regular time-based events as reminder, with tests being undertaken at these milestones, regardless of the amount of sex, partners or risk that had occurred since the last test was taken. Others tested with greater regularity, such as every three to four months, but would test more frequently if there were cause to do so, such as symptoms of STIs, or there had been an incident that had concerned them.

Around a third of men tested entirely outside of a frequent time-based routine but rather only did so following an episode of sex that occurred which they felt warranted a test, such as condom-less sex with a partner of unknown HIV status. In these instances, an

HIV test was retrospectively checking back on an incident that had occurred in the past - a desire to 'be on the safer side'.

“ [Unprotected sex] just ended up happening. And I thought ... I'm probably OK but I just want to double check ... um ... I just want to make sure I'm OK ... and that's why.” (Philip)

For a smaller number of men, taking an HIV test was (also) prospective and was used as part of the forward planning for (unprotected) sex. This was used to inform decision-making around sex in longer-term relationships to establish HIV sero-concordance with a partner, but also used to inform decisions about condom-less sex with some casual partners.

“It wasn't because I suspected anything bad, no. At that time I actually had a friend coming from [name of country] and he was going to stay for a month and he was saying 'can we have sex? Can we go without condoms?' and I was saying 'OK but only if we do the tests right now' ... so yeah ... that was part of the timing, why.” (Francis)

A narrative reoccurring throughout the majority of men's interviews was the sense that regular HIV testing was an important part of a man's health. Testing was portrayed as the right thing to do, a sign of being responsible to maintain one's own health and wellbeing, with testing being normative, and easy to do. Overall, however, men's decisions to test were rational and pragmatic, based on frequency of sex, partners or risk or duration of time since the last test. Given recent drives to increase men's frequency of HIV testing and knowledge of status (Yin et al., 2014), these results highlight the centrality of HIV testing in contemporary HIV prevention, within key groups of MSM (Witzel et al., 2015). They also indicate the extent to which men use testing pragmatically, and sometimes imperfectly, to limit the likelihood of them acquiring HIV.

4.3 Men's explanations and accounts of sex without condoms

In order to understand the potential impact of PrEP use on men's perceived risk taking and sexual negotiation, it is important to frame PrEP within the context of men's current risk taking and their accounts of SWC. Exploring how men contextualise risk-taking within their sexual lives assists in framing if and how PrEP might contribute to men's

perceptions of, and response to, risk – for themselves and their sexual partners. Given the criteria of the study’s inclusion, all participants had had SWC on at least one occasion in the year prior to interview, and were asked to describe their most recent episodes of SWC. While for a few, sex without condoms was a simple matter of not being able to establish or maintain an erection while using them, for others complex psychological and inter-personal factors influenced their ability to utilise condoms effectively and consistently. Their narratives fall broadly into two categories: those of control, consent and pressure (forces external to the individual); and those that relate to perceived personal and psychological mechanisms, including that which men simply considered inexplicable.

4.3.1 Control, consent and pressure

A common theme related to men’s (in)ability to cease sex without condoms during moments of sexual arousal. This was especially the case when the other partner (rather than the man being interviewed) was instigating or suggesting the condom-less sex. Around a fifth of men spoke of being pressured into having SWC, including instances of condoms being removed prior to insertion, or during anal intercourse.

“That struck me as a particular incident because I was saying ‘hey condoms’ and he was saying ‘hell no’ and in the past couple of years that has happened to me twice. There was one occasion when someone actually pulled the condom off and tried to shove it in me. Um ... That really weirded me out too much.”
(Francis)

Building on the issue of control, four men recounted the role that drugs or alcohol played in their sexual decision making, often combined with being on holiday, or away from home for work or pleasure. In these circumstances, men described situations when drugs or alcohol adversely impacted upon their perceptions of risk, or their capacity to respond to and to be in control of risky situations. In two instances, men recounted how being away from their home environment provided a setting where more drugs and alcohol could be consumed than usual (in part because they did not have to be at work the next day) and where those drugs facilitated types of sex that they would not otherwise indulge in.

These notions of control were not restricted to any one group of men but were more common in younger rather than older participants. Situations when participants struggled to control their sexual safety most commonly occurred when sex took place with men that participants were unfamiliar with or when an agreement had not already been established about condom use. In these circumstances, the pressure exerted to have SWC was obvious. However, one participant, who occasionally sold sex, recounted how clients regularly attempted to pressurise or coerce him into having SWC in a more covert way. Despite agreements about condom use being established prior to meeting, he recounted the occasions when men would start with condoms, before removing them part way through sex, and, on some occasions, would then attempt to ‘bargain’ a higher payment for condom-less intercourse.

4.3.2. Psychological rationales and personal values

What might be termed ‘psychological’ explanations for SWC were provided by one-third of the men, who felt that issues such as low self-esteem and depression had negatively impacted upon their ability to negotiate condom use in the manner they would prefer. For one man his (regular) condom-less sex was explained as ‘an element of self-destruction’ linked to challenges with depression and doubts regarding his self-worth. Three men indicated that SWC was enticing for them because it was transgressive, or was about breaking the rules or was seen as taboo or, in Javi’s case, forbidden.

“I don’t want to be infected and that sounds crazy because I really shouldn’t be exposing myself but I really get off on unprotected sex, probably because it’s forbidden. It’s so bizarre. It’s so fucked up.” (Javi)

For two of the men, the calculated risks they took were informed by considered views on what it is like to be diagnosed with HIV in the twenty-first century. Both had had partners with HIV and both were well informed about the impact of an HIV positive diagnosis. For Marc, having lived through a history of HIV, his reasons for reducing condom use were based upon a framework of understanding risk that, for him, was clear and rational:

“I guess at 45, I know a lot of people who are HIV positive and healthy, and the last thing I want to do is get HIV ... I don’t know a single person aged 45 who has died of Aids ... I’ve got friends who died in car crashes ... from cancer ... a

brain hemorrhage ... do you know I don't know a single person who has died of Aids and to be 45 and have been actively gay since my early 20s is ... you know, I grew up in the eye of the storm. I was 17 and I remember thinking I knew I fancied guys but there's no point pursuing it because I'll start seeing other guys and I'll get Aids and I'll die ... and then the whole 80s things and then the 90s ... and to be honest with you I'm just bored of condoms too. It's been twenty-five years. You know what I mean? It's got to the point now when you think the risk is lower and that's part of my thinking. I'm bored with condoms. I'm bored with the whole thing ... the risks are lower.” (Marc)

For Marc, the reality of HIV in the twenty-first century had shifted his perception of risk and the appropriate management strategies. With the passing of time, and decreases in HIV related morbidity, the attention paid to the risk of infection was subsumed by other more pressing personal factors, such as pleasure or desire. A few men could be frank about how concerns regarding pleasure consciously informed their risk management, while others talked of more implicit, subconscious processes that appeared to guide their behavior ‘in the heat of the moment’.

“Yeah, I have [had unprotected sex]. More by accident than by design. I was in a sauna with a guy. Started pawing around... tries to shove me up his butt ... um ... and I was like ‘calm down’ and reached for [a condom] and he was like ‘you don't need to’ and sat down ... and there comes a point when you don't want to stop.” (Francis)

Over half of the men interviewed simply felt that the condomless sex they had ‘just happened’. It was not pre-planned or negotiated in advance, but took place in the ‘heat of the moment’ for reasons that could not be easily articulated but largely appeared to relate to a dominance of sexual desire over cognitive risk appraisal. In describing their risk encounters in such a way, men were drawing upon commonplace and widely accessible discourses of risk-taking that, they believed, did not require explanation.

A number of men highlighted the conflicting nature of their sexual activity verses the types of men or sex they were seeking: men who were actively seeking unprotected sex were avoided; yet unprotected sex was (subconsciously) sought. This played out in a complex dance of ambiguity between desire and ambition: avoiding men seeking SWC but actively seeking, or hoping for, SWC.

“It's a very conflicted line because I'm finding that protected sex I don't enjoy any more, if doesn't turn me on, I can't really perform. It's not something I find

myself wanting to pursue and if I get talking to some relative stranger and they are like 'hey, let's bareback' that turns me off because it tells me they are far too casual about it and if I get talking to someone who is like 'I never bareback' that turns me off because I know I'm never going to have a good time. So ... there is no middle road between someone who never bare backs does and someone who does." (Louis)

For most of the men whose SWC with irregular partners was not pre-planned, the sex was regretted, and sometimes, but not usually followed by discussions about HIV status and concerns related to sero-conversion with the man the SWC had occurred with.

In summary, in attempting to explain their experience of SWC men acknowledged that their reasons are complex, often not static and can change over time. Men's explanations for SWC are just that: their own explanation (and sometimes justifications) for their sex, that are likely to be far more complex than summarized here or articulated in a relatively short interview. However, how men account for their SWC offers interesting implications for potential PrEP use and acceptability. Whilst the potential implications for those offering physiological explanations might be easier to comprehend ("*PrEP might enable me to get an erection and ejaculate*") those offering psychological justifications offer more complexities: if a man's rationalisation for SWC centers on a desire for risk (consciously or otherwise), or transgression, to what extent would PrEP offer any attraction?

Having explored men's explanations and accounts of SWC, the chapter moves on to explore how men manage their HIV risk in reality through a process of shifting and sometimes complex risk reduction strategies.

4.4 Reducing risk – strategies and complexities

To understand if and how PrEP might be used by men to manage the risk of acquiring HIV, it is important to understand men's current strategies for reducing risk during sex: how they are successful; how they are challenging; and if or how PrEP might be integrated into the management of risk in their sexual lives. As might be expected, men's strategies of risk management are complex, multi-faceted, and are often situational: with regard to the types of partners men are encountering; where sex is happening; and the type of sex that is taking place.

Two or three participants each mentioned one or more of the following strategies that they believed helped to reduce the risk of acquiring HIV: the age of their sexual partner (i.e. younger men were seen to be less likely to have HIV); avoiding sex altogether with known HIV positive men (i.e. ‘sero-sorting’ their sexual partners); taking into consideration the types of settings that other men use for sex (e.g. avoiding sex with men who use saunas or sex on premises venues – perceived as frequented by a higher proportion of HIV positive men); the duration of sex (shorter periods less likely to result in HIV exposure); and reducing the numbers of sexual partners, and thus the probability of having sex with a risk of HIV transmission. While these approaches may decrease the likelihood of acquiring HIV to a certain extent, these strategies tend not to be actively promoted as risk-reduction approaches for MSM within the field of sexual health promotion (although some community organisations have encouraged men to reflect on duration of intercourse and their turnover of sexual partners).

However, more commonly mentioned strategies were: (1) considering the viral load of an HIV positive partner (as a HIV positive man who has an undetectable viral load is less likely to be infectious):

“One guy in particular ... I knew he was HIV positive ... [and] he was really, really clued up on his treatments and ... so him putting his cock inside me without cumming seemed that the risk was minimised and he seemed to know what he was talking about. So yeah, we had that conversation.” (Duncan)

(2) Considering the modality of intercourse (an insertive partner is less likely to become infected); (3) withdrawal prior to ejaculation during anal intercourse;

“To be honest if I’ve gone to the stage when I’m having anal sex with someone without a condom then I’d expect for them to cum in me ... and I find it wonderful ... and the only time when I’ve stopped it is when I hadn’t intended to have sex with someone without a condom ... and we started and I’d pushed them to stop.” (Mattie)

(4) Limiting sex without condoms to regular or known partners (whose HIV sero-concordance they feel surer of); and (5) discussion of HIV status prior to intercourse (an active form of sero-sorting for both HIV negative and undetectable HIV positive men).

“If I’m talking to a guy online I’ll tell him I prefer bareback sex ... I’m fairly relaxed about it to be honest ... I’ll tend to say, what do you prefer sexually, I’m negative. If he’s negative and tested then I’ll have bareback sex with him ... and if he’s positive and undetectable ... that is generally the same ... the same thing. If he doesn’t know that will go for me in the dangerous corner ... I’d rather someone said he was positive. Doesn’t know is kind of the worst one for me because it means they don’t know. They don’t care.” (Marc)

These strategies were not used by all men or at all times, but rather were determined by the unique factors within the sexual setting, including their desire for different sexual acts (such as being receptive or insertive during anal intercourse) or what they felt might be efficacious in terms of risk reduction with particular partners. For example, many men were distinctly uncomfortable with the notion of withdrawal prior to ejaculation with men *known* to be HIV positive:

“I wouldn’t let a guy who said he is positive cum in me. I just wouldn’t do that. Um ... because that is obviously the maximum level of risk and I just wouldn’t go that far.” (Duncan)

Participants also frequently made a distinction between the kind of sex they might have, and the risk reduction strategies they might use, with romantic or otherwise regular partners compared to casual ones. Almost half of men discussed the type of sex they do or have had with regular or monogamous partners as a risk reduction strategy in and of itself. This included restricting all sex or SWC to one or a few regular partners; or being in a (sero-discordant) monogamous relationship. In some instances, men described a continuum of sex that started with a regular partner and lead to SWC, followed by a discussion about HIV, and going for an HIV test, once there was a realization that the relationship was steady.

“We started off with oral sex but I wanted to take it a bit further. Basically I wanted to swallow. So that’s when I asked him, that I’d love to do it for you but I need to know that you are OK. And that’s how we discussed and actually had unprotected sex and I fancied him ... fancied feeling him inside me ... and that was before the HIV test.” (Yan)

Discussion of HIV status also played a role in risk management for men not in regular sexual partnerships. Four men discussed how HIV status would usually be discussed prior to meeting, with mention of how websites facilitated such discussion, by enabling men to state HIV status in their profiles. However, disclosure of HIV status was not

always a determining factor in deciding whether to have SWC, again often with other risk reduction strategies coming in to play. Other men used post-hoc discussion of HIV status or discussion during sex either to reassure them that the sex was ‘safe’, and this might lead them to altering or ending a particular sexual activity. Almost all mentioned the fallibility of these approaches either because they thought that men could not be trusted to tell the truth, or because they understood the unreliability of men being uninfected after their last previous HIV test.

“When you both have that discussion of ‘you are clean aren’t you?’ ... um ... and last time I was but there aren’t any guarantees and the same with him as well. I’m not stupid but it doesn’t stop me.” (Colin)

Almost all participants had recognised that their sex was potentially exposing them to HIV. That is, that their risk taking was cognisant. Much has been written about how cognisant risk takers understand and manage their risk, albeit imperfectly (Henderson et al., 2001; Keogh, 2008; Grov et al., 2015). But for a man to manage HIV risk, he needs to be able to make an appraisal of that risk. For three participants, the shortcomings of risk appraisal, made it harder for them to employ sophisticated risk reduction strategies because they failed to understand that their SWC might be sero-discordant. Such naïve risk takers pose particular challenges for HIV prevention in general and PrEP health promotion in particular. This issue of naïve risk taking is discussed further in Chapter 8.

Each of these post-hoc rationalisations of how men manage risk during SWC provides further understanding of why and how men might find PrEP acceptable. The continuum of risk strategies utilised by men, especially with regular or monogamous partners, provide particular opportunities for PrEP acceptability and use. Using PrEP at the start of a relationship potentially adds to that continuum (start with PrEP; test; negotiate; move to SWC) or, as seen with men in known sero-discordant relationships, adds to the continuum at a later stage (for example, start with sex with condoms; move to PrEP). Such patterns of PrEP use, alongside other risk reduction strategies, that shift according to relationship status, or other situational factors, including men starting, stopping and re-commencing PrEP use, is being reflected in PrEP demonstration projects (Grant et al., 2014; Liu et al., 2014).

It is telling how imperfect each of the strategies described by men is and the uncertainty that exists for each. In section 4.4.2 below, how men might use PrEP alongside these risk reduction strategies is explored, along with how PrEP might assist in removing that uncertainty. How participants have considered or utilized another bio-medical technology to reduce post-risk uncertainty is explored as a further HIV risk reduction strategy.

4.4.1 Post exposure prophylaxis (PEP)

PEP is the only existing bio-medical prevention technology currently available to reduce HIV transmission for uninfected individuals in the UK. While most other risk reduction strategies in this section may be pre-determined (or at least used at post-facto rationales to suppress the association of risk), PEP is the only method that is usually only considered after an event of recognised risk taking. PEP is 28 day course of anti-retroviral tablets taken within 72 hours of exposure to HIV and has been available on the NHS for over a decade. Although its use is relatively uncommon, increasing numbers of MSM have accessed it (EMIS, 2013), following sexual exposure to HIV (or assumed exposure). Men in this study were asked about their knowledge and use of PEP, not only with regard to a post-hoc risk reduction strategy, but how knowledge or attitudes to this existing technology might shape men's views and attitudes to future technologies, including PrEP.

Almost all participants had heard of PEP and their knowledge about PEP was generally high, with their opinions of it largely shaped by other men's accounts of using it. When men had heard of PEP and considered using it, but not sought it (around half of participants), their reasons generally surrounded a perception that their risk had not been sufficient to warrant taking it, or they had been medically advised not to take it. A small number of men were also concerned about availability of access to PEP; raised concerns about its effectiveness, or side effects; were concerned about being judged for accessing it; or had decided that it was not the right time to take such medication. Five men *had* accessed PEP and taken it, three of those men described negative experiences of being on PEP, and two of these felt that the side effects reduced the likelihood that they would seek PEP again in the future. These men's narratives of taking PEP, and their mostly negative experiences of it, chime with those that the men who had considered PEP, but

not taken it, recounted from their peers: that the side effects of PEP outweigh the potential benefits of being on it.

“I’ve heard that the side effects can be really horrendous and you have to do it for a month or something. I had a friend who did it and he was sick every day and he just felt so ill. And so I thought ... well ... I’m not willing to put myself through that for something that is actually ... when I talk about high risk ... is still hundreds if not thousands to one against that I’ve been infected.” (Duncan)

These findings are illuminating with regard to men’s knowledge of currently accessible prevention technologies. Not only does this indicate the source of men’s PEP knowledge (other men and peers), it indicates that men’s views of PEP are informed and influenced by other men’s PEP experience. That is: men are put-off accessing a technology that is almost wholly influenced by a narrative that describes PEP as unpleasant, and that side effects seem to have been rarely mitigated or reduced by health professionals prescribing PEP. That almost all participants had a reasonable knowledge of PEP demonstrates the capacity to promote biomedical interventions to key at-risk communities.

4.4.2 The potential impact of PrEP on risk reduction strategies

Looking across the range of currently available HIV risk reduction strategies, it is evident that men chose different strategies, at different periods of time, and during different ‘seasons of risk’ (Newman, 2015a); the concept that periods of risk are not constant and consistent and may move through ‘seasons’. As will be explored further in Chapter 5, different PrEP methods might be used by men during those different seasons of risk, thereby expanding and drawing on the strategies that men are already employing. As such it is likely that PrEP will build on and develop existing risk reduction strategies, rather than create entirely new ways of managing risk.

However, for risk reduction strategies to be utilized, men need to recognize the potential risk of HIV exposure. Whilst almost all of the participants in this study recognized that they were engaging in some level of HIV exposure risk (even if that risk was underestimated), a very small number of men, failed to recognise that the sex they were having might be sero-discordant. The challenges of PrEP use, and indeed other risk reduction strategies, for naïve risk taking men, is explored in further detail in Chapter 8.

Most participants recognised the imperfections of their current risk reduction strategies, and that they frequently offered uncertainty – one of the dimensions of men’s post-hoc HIV testing. It is worth considering if one of the attractions of PrEP might be the increased certainty that PrEP might offer, when used alongside or instead of other strategies.

4.5. Chapter summary

In this chapter I have addressed participant’s narratives about how they manage their sex lives: how sex is sought and encountered; how HIV testing is used to manage pre-sex decisions and to offer post-sex reassurance; and how a range of risk reduction strategies are drawn upon to mitigate HIV risk. The fallibility of these strategies has been addressed, including that of HIV testing, and knowledge of status, and have highlighted how men need to be cognizant of their HIV risk to most effectively draw on these strategies. Whilst most men understand and are cognizant of the risks they are taking, albeit if their management of risk is imperfect and offers uncertainties, a small number of men – naïve risk takers – do not, or do not want to, recognise the risks they are taking and, as such, do not appraise that risk or modify their strategies accordingly. Such naïve risk taking offers particular challenges to the uptake and acceptability of PrEP.

In the next chapter, the way that PrEP could be positioned in men’s lives is carefully examined.

Chapter 5: Results - Positioning PrEP in men's lives

In this second results chapter, participants' *immediate* considerations regarding willingness to use daily oral PrEP is considered and their understandings of the perceived impact and utility of PrEP. This is contextualised through men's narratives of sex and risk, intimacy, opportunity and pleasure. The reporting of this first initial discussion of willingness to use PrEP focuses on daily oral PrEP and then moves on to address other PrEP methods, including acceptability dimensions that are unique to particular PrEP methods. The chapter moves on to examine the centrality of PrEP efficacy in how men consider PrEP, before concluding with an exploration of how men might navigate or negotiate their own and other men's PrEP use.

5.1 Knowledge and initial reactions to PrEP

In this first section, participant's knowledge of, and their initial reactions to, PrEP are examined. While further exploration of concerns, potential challenges and possibilities occurred later in the interviews, men's initial thoughts on (oral) PrEP, including their willingness to utilise it were enlightening. In the section that follows participants reflect where they are *now* in relation to their PrEP knowledge and use, as opposed to where they might be in the future.

5.1.1 Knowledge of PrEP

Participants were asked if they had ever heard of PrEP, to recall the source of their PrEP knowledge and to describe what they knew. If they had not heard of PrEP, the technology was described to them, and they were asked again if this was something they had heard of.

The responses obtained demonstrated significant variation in men's prior knowledge of PrEP and the manner in which this knowledge was obtained. While a small proportion (around a quarter) had what might be considered an in-depth knowledge of PrEP, in that they had deliberately accessed and digested information about it from sexual health clinics, journal or media articles, around half of the remainder had only a basic understanding. Often this amounted to perceiving PrEP as "*like a contraceptive pill*" (Colin) or a vague understanding that PrEP could allow sex without condoms. Many had drawn understanding from global news coverage of the topic (in both gay and

mainstream media), while others had discussions with friends or were simply informed by their involvement in the Sigma Panel. Only four participants said that they had never heard of PrEP and could not recall ever hearing about it when prompted.

Crucially, men's knowledge of PrEP appeared intrinsically linked to their proximity to HIV: men who had a primary partner with HIV, or who had knowingly had condomless sex with an HIV positive partner, were more likely to know about PrEP in general, and more likely to have a detailed knowledge of PrEP. Such men were more likely to have had conversations about PrEP or have sought out further information. Conversely, men who *considered* they had less proximity to HIV (even if an objective assessment of their sexual behavior suggested this may not be the reality) were broadly less knowledgeable about PrEP.

5.1.2 Potential PrEP use

The key headline findings of the iPREX trial were presented to participants (see Appendix 6), with an opportunity for discussion and questions about the study. They were then asked, on the basis of this information, if they would consider taking daily *oral* pill to prevent HIV infection, if such a technology became available in the UK. These initial views on potential PrEP use relate only to daily oral PrEP and reflect participants' *initial* perspectives on potential PrEP use. As will be seen later in this chapter, men's views about PrEP use tended to become richer and more detailed as they were presented with details about different PrEP methods and when participants had further opportunity to consider a concept that was new to many of them. Participant's perceptions of other PrEP methods are reported below.

One man was already accessing PrEP independently (not through a clinical trial) and another had previously sought PrEP through his sexual health clinic and responded favourably to taking, or continuing to take, a one-a-day pill. Five further men immediately responded that they would want to take PrEP in this format, even if they some had reservations about it (see below).

“Would I use it? Um ... I personally would personally. Probably. Absolutely!”
(Francis)

Over one quarter of participants said that they would not consider using a daily pill at this time, either because they thought that their risk was currently insufficient or because they did not want to use a medication that they felt was not needed by them.

“I don’t think I’d want to put a drug into my system that I don’t necessarily need. I wouldn’t feel comfortable taking something when it isn’t really something I need, I guess.” (Ed)

One man raised an immediate concern that PrEP might be protective against HIV but not other STIs and another raised concerns about his potential elevated risk taking on PrEP (see below). Most of these men described how they might consider using PrEP in the future if either their circumstances, or availability of information or evidence about PrEP changed.

However, as many participants felt that a one-a-day pill would be something they would currently consider but they would want to weigh up any possible consequences of taking the daily pill, or wanted to consider further information about taking daily oral PrEP. Especially for men who had little PrEP knowledge, they would want to explore the concepts and potential risks of taking PrEP. Two of those men raised initial concerns about possible elevated sexual risks that they might take if they were using PrEP, either through decreased condom use or by switching the modality of the SWC they have. For each of these men, thought was given to how they currently manage sexual risk, and their ambiguity towards PrEP was balanced and played out against that current risk management.

A decision to take PrEP in the future was also considered circumstantial – depending on relationship status; if one increased sexual activity or had more SWC; and if a man started to date or have sex with a known HIV positive partner.

Men were also broadly more likely to hold more positive views about PrEP, and its potential, and sometimes its downsides, if they had closer proximity to HIV. It is worth noting that being proximate to HIV, in and of itself, might not necessarily lead to greater acceptability of PrEP. Although this research did not interview men with diagnosed HIV, research suggests that some people with HIV raise not insignificant concerns and doubts about PrEP use (Saber et al., 2012; Frankis et al., 2014) that might

impact on negative peer and partner views of PrEP. As Chapter 6 will show, HIV positive peers and partners of men I interviewed were believed to have broad and disparate attitudes to the acceptability of PrEP.

From the accounts in this study, we can surmise that men that have been, or could have been, involved in HIV exposure, are broadly willing to consider using a daily pill to prevent HIV. One-third of men in the study said that they would currently not consider using PrEP, with a further third of men considering PrEP a possibility, and one third saying that they would take PrEP now, if it became available. These levels of willingness to consider using PrEP are broadly comparable with existing community surveys and studies that indicate that around a half of MSM surveyed would consider using PrEP (Aghaiz et al., 2012; Frankis et al., 2014; Sigma Research, 2011; Thng et al., 2012; Young et al., 2013).

5.2 Perceived impact and utility of PrEP

Interview participants were asked to describe the perceived potential impact of PrEP on their lives (and the actual impact of PrEP use for the one current PrEP user).

Participant's narratives can be broadly divided into two (overlapping) themes: the way in which PrEP may influence sexual behavior and risk-taking; and the experience of intimacy and pleasure within sexual relationships and the opportunities this may afford. These are explored in turn below, with further detailed narrative on the interpersonal impact of PrEP on sex and risk management in section 5.6

5.2.1 Sex and risk

Significant lengths of time were spent within the interviews considering how PrEP might impact on the type of sex men have. If discourse did not arise naturally then participants were directly asked to consider how PrEP might impact on their existing risk reduction strategies. Three men articulated that they were fairly confident that PrEP use would not have an impact on their condom use. Javi felt that his current level of risk would not change because the potential reduction in risk from PrEP was not sufficient and Jovan said that he was content with his current risk levels and could see no reason for changing it. And Alex thought that although he might be more relaxed about the sex he would have, he did not perceive any likely fundamental changes.

“No. I don’t think so. No, I don’t think I would. I think I might be slightly more relaxed about it but not like ‘great, I’m on PrEP let’s go and get bare backed by 40 people or whatever’.” (Alex)

However, half of participants said that they were certain or fairly confident that PrEP would reduce the occasions when condoms were used during anal intercourse. For one man, this made PrEP totally unacceptable for him, as it would result in levels of risk that he was not happy with.

“I doubt I would do it purely because it would change the risk assessment of things I would do. It would make me more inclined to take more risks with unprotected sex.” (Jos)

Two thirds of participants raised the potential increase in exposure to other STIs as a consideration of PrEP’s acceptability to them personally. Almost all of these participants articulated that they thought availability of PrEP would lead to a population increase in STIs, although fewer men were so confident that this would be the case for them personally. Although only one man felt that potential exposure to other STIs made PrEP unacceptable to him, other men weighed up the benefit of PrEP versus the cost of potential STI exposure. Three men took a pragmatic approach and acknowledged that, for them, HIV was, as described by one man, *“the big one”*, and although STIs might increase, at least PrEP mitigated against HIV.

“It would ... at least rule some of the worst case scenarios out. I know I would still catch other serious STIs. But everyone you rule out is one you rule out, right?” (Francis)

These men viewed the more common STIs as easily treatable with one man articulating that, given that PrEP might be most attractive to men who took risks anyway, STIs were inevitable whether men used PrEP or not. Other men – especially those who had previously experienced an STI – did not want to underplay the issues and were concerned that HIV might overshadow the implications of other STIs.

“Um ... the other thing is ... it would be eminently stupid just to take that tablet [without thinking about other STIs] because there are a lot of things you can get. You can get pills for almost all the other things but anyone who has ever had a shot in the arse for syphilis never wants that again because it’s agony! And you know ... you forget ... HIV is the spectre at the feast but there are little

demons hiding under the table and good god I never want to have that again! That HURT! Um ... I really, really don't want to have that again." (Colin)

Others felt that using PrEP might present greater opportunities to reduce or diagnose STIs. One man argued that PrEP use would offer an opportunity to discuss PrEP generally **and** an opportunity to discuss if a partner might have other STIs. For another, regular clinic visits for PrEP would help to reduce undiagnosed STIs, as there would be increased contact with clinical services. Still further, those men who saw themselves as the least risk takers - those who had SWC infrequently and/or only with regular partners - saw STIs less of a risk personally because their sexual practice reduced likely exposure.

A few men raised concerns that, although their own condom use might not change with PrEP, other men's would and this would lead to a population increase in STIs, therefore making him more likely to be exposed to STIs.

"Well, personally I would be concerned. And this is great ... you don't want to contract HIV ... but you don't want to contract gonorrhoea or syphilis either. But ... I think those people who are happy to have something like this are not really concerned if they pass anything on to others." (Yan)

Two men raised the issue that increased exposure to STIs may increase their susceptibility to HIV transmission, even if on PrEP, or increase the viral load of an HIV positive partner. In general, men recognized that there might be a potential play-off between an individual or population HIV prevention benefit in prescribing PrEP, at the expense of a population increase in other STIs. For Roy, this highlighted the importance of ensuring that any PrEP awareness work was embedded within a broader sexual health and STI prevention framework.

"That's the million dollar question isn't it? You've got things like hepatitis [C] that you can't cure ... so I think there would have to be an awareness or protection programme that says 'yes, you're protected against HIV but these are all the other things you need to think about.'" (Roy)

The risks of STIs that these men refer to highlights the extent to which condomless anal intercourse was held by some to be intrinsically risky. Ed articulated that in the context of PrEP being available he "*probably would be a bit more blasé*" about using condoms,

whereas Max considered that “*the pretty impressive drop*” in HIV acquisition on oral PrEP would probably result in less condom use for him personally and, therefore, greater ‘risk’ taking. For Colin, PrEP would give him more control over his sexual health, even if it resulted in using condoms less often.

“This type of tablet enables you to take more control of your own sexual health. Would it make me take more risks? Probably. Certainly. Forget probably – certainly! If I was on holiday in [name of place] and had been taking this every day of the week I’d think ‘fuck it!’ and go in to [name of bar] of a night and ... um ... come find me in the morning with a mop, you know? That’s sort of what would happen.” (Colin)

Generally, these men took a considered view that, although SWC might increase, the protective nature of PrEP would cancel out that (HIV) risk. However, some were still keen to mention their other risk reduction strategies, beyond condom use, and these might be incorporated into sex while on PrEP. Duncan felt that, as he had established that being a top (being insertive) carried less of a risk than bottoming (being receptive), if he went on PrEP he would “*probably start doing that with complete gay abandon and not feel too guilty about it*”. Other men felt that they would continue to discuss HIV status or viral load of partners; or would continue to employ other strategies such as withdrawal before ejaculation or considering modality of intercourse should they have SWC on PrEP. For Mattie, he would continue to employ a strategy of avoiding SWC with someone he knew to be HIV positive. In doing so he draws a clear distinction between sex with a theoretical risk of HIV exposure and sex where he *knew* he might be exposed to HIV.

“If a guy told you he was HIV positive and you were taking PrEP, do you think that would change the kind of sex you have with him?” (WN)

“No. No. I wouldn’t have unsafe sex with anyone if I knew he was positive. Um ... I wouldn’t do it.” (Mattie)

For two men, their consideration about whether PrEP would diminish condom use was tempered by consideration about adherence to PrEP. For Simon, there was a concern that he would not be sufficiently protected because of forgetting to take pills.

“I don’t know is the answer. I don’t know how well I’d be at taking it every day and so I don’t know how it would impact on my sex life ... if I’ve taken it every

day and then become paranoid that because you haven't taken it and catch [HIV].” (Simon)

Whereas for Yan, complete adherence and ensuring that he was fully protected by PrEP might well be the point when PrEP could have an impact on his sex life.

“What if you were really adherent? Taking it every day and using it consistently?” (WN)

“Hmmm ... yeah probably I would risk it ... I would.” (Yan)

“You think you would use condoms less often?” (WN)

“Yeah. (But) I'm not going to turn into a complete bare backing slut! No! No!” (Yan)

Yan's response here perhaps sheds light on entrenched anxieties relating to prevention techniques that are reliant on a daily regimen, leading some participants to question or observe their own fallacies (a point which is re-visited in relation to intermittent PrEP dosing).

Despite concerns by some men of the potential to increase their own, or a broader community sexual risk, participants also voiced the potential for PrEP to offer opportunity and pleasure. It is to this that the chapter now turns.

5.2.2 Intimacy, opportunity and pleasure

Over one quarter of participants identified that PrEP might have a positive impact on their experience of intimacy or pleasure, both highly valued aspects of sex among most of those interviewed. PrEP also might allow for the performance of different sexual acts, which may have been considered too risky previously. In addition to potentially overcoming some of the physiological barriers to sexual health management, men identified the potential for PrEP to open up opportunities for the sex they have, or who they have sex with. Philip could see the potential to have a relationship with a man with HIV if he used PrEP:

“I do tend to like guys who are positive. Um and so ... it could open up possibilities of having a relationship with somebody ... because the whole thing is I want to have unprotected sex with my partner and that rules out sex with guys who are positive. This would make it an option.” (Philip)

Around a third of participants felt that PrEP might reduce anxieties or stress relating to sex, which would have a positive impact on their experience of it. For Francis, PrEP offered an opportunity for greater intimacy and a reduction in exposure related stress during sex with his HIV positive partner, which could have significant benefits for their relationship:

“To go without condoms ... that would be a pretty amazing thing for our relationship. It’s always been a stress that we’ve never been able to do that, that we’ll worry about it. And more likely that we’ll consider each other as sexual partners. It takes away the fear that he’ll infect me and that’s something we both have in the back of our minds. We’ve never been able to get that close in almost a decade and a half. [PrEP’s] a very, very significant thing, yeah.” (Francis)

This was a view shared by a number of other participants in a primary relationship with an HIV positive partner who felt that at a very holistic level, PrEP could have a positive impact on their relationship and how they could feel intimate with others over the long term. For other men, PrEP could be seen as reducing anxiety *during* sex (that is, men could better enjoy sex knowing that they were protected) and post-sex, especially in circumstances when SWC was unplanned when men might be *“less worried about having had a slip-up”* (Mattie). Those men experiencing regular mental health issues that they associated with risky sexual behaviour also saw potential for using PrEP during periods of depression.

“If I was in a depressive cycle and I was at risk ... having that in my drawer would be a peace of mind ... knowing it was there.” (Philip)

A striking narrative for participants who felt that PrEP might offer more intimacy or pleasure, or that it might reduce stress, was less that PrEP might offer greater HIV protection, but that not worrying about HIV – or worrying less – might lead to better sex and a more healthy sex life in general. That men view PrEP within a broader context of holistic sexual health offers opportunities and challenges for how PrEP might be prescribed, and the contexts in which it is available. This is discussed further in Chapter 8.

In summary, participants gave an initial reaction to the perceived utility of PrEP that was carefully considered. For the half of men who considered that using PrEP might

increase the occasions when they had SWC, they understood that either within the context of the protective nature of PrEP (at least for HIV) or alongside their current risk reduction strategies. Others considered the impact of PrEP on sex and risk within the context of adherence and PrEP efficacy. Men's views on PrEP and risk were broadly considered, often cautious and framed within their current knowledge of, and analysis of risk. As with the risk strategies reported, these considerations were sometimes overlapping and imperfect. What is telling is that despite contemporary discourse on the (negative) impact of PrEP on sex and risk (Garner, 2012; Stern, 2014b), participants articulated the potential opportunities for PrEP to increase opportunity, intimacy and pleasure, particularly in circumstances when men had a known HIV positive primary relationship. I return to this theme in Chapter 8.

5.3 Perceived practicalities of PrEP use

This section explores the acceptability of PrEP for this sample across a range of dimensions. These relate to practicalities that men often felt could have a significant impact on their daily lives. These relate firstly to the implications of repeated and regular clinical interaction (a likely requirement of PrEP prescription), and secondly to the regimens of pill taking and concerns relating to drug resistance. For each of these, men's acceptability with regard to daily oral PrEP is explored first and, where men gave narratives that pertained to other PrEP methods, these follow. Whilst it is apparent that some dimensions of PrEP acceptability are shared across all PrEP methods, some dimensions are more unique to particular methods. For example, participants raised no *method-specific* acceptability issues regarding taking medications or drug resistance but particular acceptability dimensions for daily oral PrEP exist, as they do for methods other than daily oral PrEP. This is especially the case for topical PrEP and slow acting injectable PrEP and these unique dimensions are addressed below in the section titled 'Body, Lifestyle and Routine'.

5.3.1 Considering the clinical interaction

During discussions on the practicalities of the availability of PrEP, all but one participant raised the issue of where PrEP would be available and how it might be physically prescribed. Most acknowledged that such medication should be regulated and made available through health practitioners. Participants were asked if making regular

clinical visits, would be acceptable to them, or if this would be a disincentive to using PrEP.

Three-quarters of participants responded that a monthly clinic visit, at least in the initial stages of taking PrEP, would be acceptable to them, and, for a quarter of men, this would be dependent on the proximity of the clinic, or the ease of access, including suitable opening times and swiftness of appointments. Four participants considered that monthly clinic appointments would not fit with their work patterns or lifestyles, usually due to travel and time away from home, and felt that quarterly visits would be more suitable. One man preferred the concept of quarterly clinic visits because he felt that more regular visits might increase his condom-less intercourse.

“I think [monthly visits] would make me use condoms less – because if I was having an MOT every month and I knew if I was getting Chlamydia or gonorrhoea or syphilis tests all at the same time then that would increase my likelihood of being unsafe. If I was 3 monthly then I think I might still have a little voice in my head about the other things. But monthly, I think I would pretty much feel invincible!” (Colin)

For four of the men who favored regular clinic visits, there was an added benefit that they would get checked (more) regularly for STIs or for possible side effects or toxicity of PrEP. For these men, regular clinic visits incentivised PrEP use and made it more acceptable and they would be reassured by being seen regularly by a health professional. Interestingly, there was no difference in the acceptability of clinic visits by different PrEP method: a further quarter of men felt that regular clinic visits to have injectable PrEP would be acceptable, especially if such visits might be expected for any method of PrEP.

“It’s an easy visit to a clinic. You get an injection and then off you go.” (Marc)

However, one man felt that he would be more likely to miss an appointment for an injection, than he would be to miss a pill dose, due to work and travel commitments. The impact of travel was raised by two further men with regard to missing injection appointments.

5.3.2 Regimens and resistance

Four men raised the issue of taking any pharmaceutical drug and how the overall acceptability of PrEP to them was tempered by their general dislike of using any medication.

“I avoid taking medicinal drugs ... even pain killers. I’ll take that only as a last resort”. (Philip)

For two of these men, this was also balanced against the relative risk they were taking. That is: if their sexual risk was greater, they would be prepared to consider PrEP and its own (from their perspective) associated risks as a pharmaceutical.

While two other men raised concerns about the possible interactivity of PrEP with the other daily drugs they were prescribed, more common were concerns about possible drug resistance emerging if PrEP was not taken correctly (including by other men on PrEP). Some expressed concern that this might limit possible future treatment options should they become infected with HIV, and how this might impact on the effectiveness of PrEP more generally in the future.

“I’d certainly be worried about some of the long term effects that we don’t know about ... There’s a worry there will be a massive change in the virus that makes this class of drugs useless in the future. It’s already given to people as a treatment isn’t it so it’s possible that this virus can beat it. Um ... so that’s a worry that the virus goes sideways on it and this particular version of PrEP is no longer efficacious.” (Francis)

A few men understood the general principle that drug resistance was more likely to develop if people are not adherent to their medication and, indeed, concerns relating to regular pill-taking for daily oral PrEP were discussed by the majority of people. Over one third of men said that taking a pill every day would not be an imposition for them, especially as most were already taking a daily vitamin or supplement pill either or daily prescription medication.

“Would I find it difficult to take a pill every day? Well ... I would have to show you my cupboard. Come, please. You’ll have to describe it later. [Moves to cupboard and opens door]. Look at that! It’s ridiculous! I take a daily pill every day! If it’s laid out I just take another pill!” (Javi)

Other men felt that taking a daily pill would simply be the reality of something like PrEP, necessary to receive its benefits, whilst one man was surprised that the regime was, to him, so simple.

Alex articulated a somewhat more complex reason for finding daily pill taking attractive; the process of taking a pill everyday might not only be protective against the sex he was currently having, but would also encourage regular reflection about the risk he is taking and how it feels about them.

“By taking a pill everyday it’s kind of reminding you what’s at risk. It might actually make me more considerate of it. I think it’s easy to forget HIV sometimes ... I think if that was a constant reminder every day – I have to take a pill, I have to take a pill – something in the back of your head might click in if you were getting in to a situation and you’d think ‘hang on a second: there’s a reason why I’m taking a pill. There’s a reason why I’m taking this ... why this behavior might be risky ... so let’s do something about it before engaging in it.”
(Alex)

A number of men found the notion of regularity in daily PrEP use particularly appealing. It was, they perceived, more likely that they could successfully integrate a once-a-day behavior into their routine – similar to showering or putting in contact lenses.

“You know ... it’s become something I do automatically. I have an alarm on my phone. I have an hour’s window. I have a couple of spare pills in my bag, you know. I take them when I get up. It’s completely automatic.” (Louis)

Only one man raised concerns relating to control in relation to daily oral PrEP. Philip disliked the concept of PrEP being regulated and available only through medical professionals, articulating that the experience might be “*degrading*” and diminish his control over his health. As such, this would lead him to think twice about taking PrEP.

“It kind of fits me into having to go and see someone to get it. It’s kind of like a [social security] benefit ... the whole experience would be a bit tiresome and it can be a bit, you know, degrading as well, so I think that ... it’s like some of those science fiction shows I’ve watched when the company owns the drug and you don’t get you next fix until you get what they say ... it’s a bit like being controlled ... you are reliant on someone else giving you the supply.” (Philip)

Further to issues of control, there were those who found other dimensions of a daily medication to be problematic including possible side effects as addressed in following section and the potential of forgetting to take a daily pill (as addressed above). The perceived (un)acceptability of daily pill taking influenced how men considered the utility or practicality of other PrEP methods. When men were less favourable towards a daily oral pill regime, the reasons were less about its inconveniences and were more to do with a man forgetting to dose daily, thereby making the medication less effective.

One-third of participants felt that the reliability of PrEP provided by an injection made it attractive when compared with pill taking, even if this was not the preferred method for all of them. This was because they understood that they (or others on PrEP) might be more likely to forget or miss a pill dose, whereas injections provided longer-term coverage.

“That would be awesome actually because I know that taking the pill is something that not everyone does. How many pregnant women are wandering around thinking they wish they hadn’t forgotten to take the pill? But if you ... then went to the clinic once a month to get an injection, that would be amazing. Yeah it really would. Definitely preferable.” (Francis)

Interestingly, both the man currently taking PrEP and the man who had previously sought PrEP, found this method particularly appealing due to the diminished likelihood of missing necessary doses. In the following quote, Louis articulates how injectable PrEP might actually reduce stress or anxiety more generally.

“Um ... yeah ... look implants would be awesome ... It really appeals to me that you can’t miss a dose. You don’t have to think about it ... um ... you know, you get a steady rate of release.” (Louis)

How injectable PrEP might be administered raised acceptability issues for a quarter of men, but in diametrically opposing directions. Two men were concerned that there might be an eventual expectation that they would have to give themselves the injection.

“I wouldn’t do it myself. I could inject my boyfriend and I could probably let him inject me. I went for bloods ... the other day and I can’t look. When I had to have all the bloods for PEP I passed out. What a wimp! We would probably inject each other. He could probably do himself. He’s hard as nails.” (Colin)

Whereas a small number of men would want to be further in control by administering their own PrEP injections and the administration of PrEP by a medical professional took away their sense of control of how to prevent HIV:

“Control is a big issue actually. The control about who is doing the injection is quite important actually – whether it’s them or me. I would feel less in control of my life if I had to go and get this injection. I would feel more positive about it if I could do it at home and looking after my own health. But I don’t like the idea of going for an injection with someone else maintaining control. [It is about] control over my well-being rather than control as in who is doing the thing, having an active part in my health rather than being a patient I suppose.” (Nate)

5.3.3 Concerns relating to side-effects of PrEP medication

Perhaps the over-arching issue relating to the physical impact of PrEP that influenced men’s personal PrEP acceptability surrounded the issue of side effects. Two-thirds of men held significant concern about this issue. Although findings from major international studies showed few side effects with oral PrEP (Grant, 2014), it still played heavily on the minds of many participants as they considered how PrEP could be incorporated in their everyday lives and, ultimately, the extent to which they considered PrEP acceptable.

Overall, perceptions of PrEP were situated within the types of side effects that men might experience – if these were mild or severe; if they were temporary or permanent – and whether the side effects would differ between short-term use or long-term use of PrEP. Whilst some men acknowledged that, unlike current HIV treatment, PrEP would be unlikely to be taken for life, there were questions about evidence on the long-term impact of taking Truvada. Men who were more informed about PrEP, or other medical issues, highlighted the short-term ness of trials such as iPREX, and that the longer term impact and side-effects of PrEP could not yet be known.

“I probably wouldn’t bother until there was more evidence to say that actually, going on this for 5 to ten years doesn’t cause any long term problems, and it’s fine to keep using it for that period of time.” (Jos)

Some men’s views about side effects of daily HIV drugs were tempered by a friend or partner’s experience on HIV treatment, or an experience of being on PEP.

“If side effects were like PEP then I wouldn’t go near any of them. I simply wouldn’t do it again.” (Colin)

For others men, a play-off would be made between the side effects and other factors. For example, one man felt that he could accommodate more side effects if he were sure the result was a more efficacious medication, in terms of protecting him from HIV. For others, minimal side effects would be worth the benefit of taking PrEP – either through sexual pleasure and enjoyment, or, in Marc’s case, a reduction in stress.

“I would want to look in to the toxicity around the drug ... just to understand that a bit more ... you know ... it would be nice to have a little bit less stress around catching HIV too.” (Marc)

A quarter of men said that taking PrEP intermittently was a preferred routine compared to taking a daily pill because of the impact of daily pills on their body, and a perception that intermittent PrEP could have fewer side effects.

“For me ... the advantage of not taking a daily pill would be, you know, to give my body a rest. For me that would be like a, you know, not overdoing my liver or kidney. For me, that would be the benefit, that I could pick and choose and, you know, ‘I’ve got a party this weekend, I’ll take this’ and then give my body a rest rather than taking the drug everyday continually which, you know, although it says there are no side effects, you are still taking a drug every day. That would be the attraction of that.” (Marc)

Only two men made mention of the potential side-effects of injectable PrEP: one was concerned that they might be greater, as an injection would give a greater dose of medication than a pill; one felt that the side effects of injected PrEP might be less because of how the body would process the drugs. Three men raised acceptability concerns regarding the potential side effects of long-acting injectable PrEP and would factor these into any future decisions about taking this format of PrEP. For one man, his rare episodes of SWC made topical PrEP most attractive, as he would only need to apply PrEP on these small occasions, rather than having a drug in his body for longer periods of time.

5.4 Body, lifestyle and routine

As mentioned at the opening of this chapter, while many aspects of PrEP acceptability were common across delivery methods, some were more specific and require discussion

on an individual basis. In the first sub-section I address: the extent to which sex is pre-planned and how this influences perceived acceptability of both intermittent PrEP and topical PrEP; sections 5.4.2 and 5.4.3 relate to acceptability dimensions that relate to topical PrEP only; and sections 5.4.4 and 5.4.5 relate to formats of injectable PrEP.

5.4.1 Pre-planning of sex

In Chapter 4, the issue of how men plan their sex lives was explored, with men reporting that they increasingly have spontaneous, rather than pre-planned sex. Perhaps inevitably, this highlighted acceptability issues for those PrEP methods that need to be taken or applied in advance of sex. While a few men felt that intermittent PrEP dosing might counter their concerns regarding pill taking and resistance, a third were concerned that as their sex did not fit around a pre-planned schedule it would be hard to identify the right time to take the medication.

“I’m not in a position when I can predict so well. It’s a nice idea if my life had that structure to it ... it could work if I knew when I was having sex you know but ... yeah ... only if I knew so it’s a bit hit and miss.” (Nate)

Some men actually felt that even if prescribed an intermittent dosing regime may actually end up taking PrEP daily to alleviate concerns about the timing of sex.

“If you have such a sex life it makes all the sense in the world. But my sex life is essentially the same except that some days I have sex and some days I don’t ... so I would have to take [PrEP] every day. I never plan that way. It just happens. It would be interesting to see a frequency diagram across the week and I think it will be a flat line.” (Javi)

However, one quarter of men said that intermittent PrEP offered a greater level of acceptability when it was considered situationally. For these men, the concept of being able to use intermittent PrEP for a party weekend, a special occasion, or when on holiday, was extremely attractive.

“Yeah, I mean, that’s kind of a good idea if you a regular party goer or if you knew that you were having a regular party weekend ... or a DJ is in town I’d like to see and I can probably think that after that I might hook up with someone. So in that way you could probably plan for it and that might be better than having it every day and worrying about not taking it.” (Alex)

With regards to topical PrEP, the issues associated with pre-planning of sex were even starker than in relation to intermittent PrEP. Half of participants found that any need to pre-plan insertion of topical PrEP made it unacceptable for them. In addition to the practical issues explored below with regard to douching and bowel movements, men cited concerns about how and where they would practically insert the gel in advance of intercourse.

“I would guess that if you were going out that night that would put you at work doing it in the toilets. That would be a hassle. Kind of annoying I think.”
(Martin)

One quarter of men said that the pre-planning of the application of topical PrEP did not fit in with how they managed finding sex, or that being so disciplined would not work for them. For Mattie, the spontaneity of his sex would make topical PrEP unacceptable for him.

“There’s too much preparation and forethought. And one of the things about sex is the spontaneity ... um ... you might be out ... in the countryside for a hike or whatever and suddenly there’s someone there and the urge takes you and, you know, pants down and spitting on your cock.” (Mattie)

Participants were more likely to find topical PrEP acceptable if usability allowed for spontaneous use, such as being used as a lubricant, rather than it having to be pre-applied.

“The idea is potentially good but I think for me that product would be really good if it was something I could apply during the act. If I was going to get fucked then I could put it in there and go ahead. Other than that I don’t think it’s going to work for me.” (Duncan)

These results suggest that PrEP methods that require pre-planning of application or planning of taking pills to account for sex without condoms at specific times may be unacceptable for some men. However, also indicated is the potential appeal of intermittent PrEP dosing to men who may not engage in HIV risk-behaviours on a regular basis, but rather those who think ahead to times or events when they think it likely they will be sexually active and would value the protective effect of PrEP on such occasions. The timing of application of topical PrEP before sex was seen as particularly

problematic, as were the more practical complications of topical PrEP use, as explored in the following section.

5.4.2 The practicality of using topical PrEP

One half of men said that the practicality of preparing for and applying topical PrEP would make it unappealing for them personally. Especially for men who were used to preparing for receptive anal intercourse, the need to pre-apply PrEP was incompatible with the cleaning and prepping regime they were used to. These men understood how such pre-application might be suitable for the vagina, but the rectum posed a set of other challenges.

“On no! You take a poo and everything is coming out. You take a poo and then you’re going to have to put [the gel] back in. It doesn’t make any sense. It makes sense in vaginas because vaginas are all about stuff going in and staying there. But here we’re talking about a two-way street!” (Javi)

Other men were concerned that topical PrEP might leak prior to sex, causing issues of embarrassment, or having to reapply the gel, or raising concerns that there was insufficient gel inside to be protective. The mess of topical PrEP was a reoccurring theme and one that posed a major dis-incentive to PrEP acceptability.

Some men were concerned about how PrEP might be contained, administered and carried by men, especially if anal intercourse was not pre-planned and, as such, was viewed as less practical than keeping pills in one’s pocket or bag. Such a dilemma were illustrated by Colin:

“What a faff! You know, it’s not easy to get something up your ass and for it to stay there. It’s not like you can just have a gel packet that you can squirt up your ass. You would need an applicator and it doesn’t fold like a packet of lube in your pocket. Hmmm ... not sure about that one. Gel? No. Not for me.” (Colin)

A small number of other men were concerned about dosage and self-dosing and, rather than seeing topical PrEP as giving men more ‘self-control’, the impracticality of topical PrEP made it less attractive than a pill.

“I guess I wonder ... how long before I am having to [apply] that ... how easy is it to do ... how easy is it to know that I’ve gotten it right? Um, I think my initial

thoughts are, I'm wondering, have I done it right? Have I done enough? Have I got it in at the right time?" (Jos)

A quarter of men raised concerns about the taste, smell or feel of topical PrEP and the impact this would have during sex. Given the necessity of applying topical PrEP prior to intercourse, men voiced concerns about the impact on oral sex and anilingus and questioned if the gel would impose on such sexual activity. One man articulated safety concerns about oral ingestion of topical PrEP during oral sex, and if this might be of danger. For one man, the sensation of pre-intercourse sex made topical PrEP unacceptable.

"The mess! You know, it's bad enough when you've got lube in your arse! Someone starts fingering you and you're full of gel – that's not going to be an attractive look is it? It's really not! No! It's going to leak and that. It's not going to be great that. It's like with being fingered and stuff ... No! That is something else up there that you don't really need to be there isn't it? No. No. That wouldn't work for me." (Colin)

Mattie raised a further concern about the impact on sex: he felt that the pre-preparation of topical PrEP imposed on intercourse, making sex somehow clinical and a deviation from sex:

"Yeah ... we're getting too much in to clinical territory ... you know if it was part of a clinical trial that would all be fine but ... when you're in the bedroom, I just wouldn't do it. Possibly if you could squirt it on the other guy's glans before he enters you, then it's possible because that's like ... it's not really deviating from normal sex. But any other deviation? No." (Mattie)

5.4.3 Noticeability and pain

Of all of the technologies discussed, longer-acting injectable PrEP, when considered as an implant, was the PrEP method that elicited particularly negative responses, common among a quarter of participants. The concept of longer-acting PrEP was considered “scary” (Philip) and “dehumanizing” (Duncan). For these men, having an implant inside them was considered a step too far:

"Instant recoil from that. I don't like the idea of being physically marked. It's almost like being branded in some way and it's um ... it feels like it is depersonalizing or dehumanizing me in some way. At some basic level it's making me think 'urgh!' ” (Duncan)

Two men raised concerns about the impact of implants during work – that the implant might get knocked, or, in the case of one participant, having to shower with work-mates might make him stand out as having an implant, if it were visible, and that would raise uncomfortable discussions at work. This theme of noticeability, or being seen by others, emerged as an issue for over a third of all men. Others seeing an implant might mean that assumptions are made about you, or about the lifestyle being lead:

“Um ... it sounds a bit silly but you don't want to publicise the fact that you're ... although you're effectively trying to look after your health and protecting others, it's almost like you're saying 'I lead a life that is risky and I'm taking an anti-HIV medication' ... and even though I'm taking it because I don't want to have HIV ... and I don't want others to have it, it's almost like saying that I'm involving myself in sex that is risky.” (Mattie)

Whereas Nate commented that this might offer an inadvertent benefit:

“I can see almost at some point like it becoming a thing that people could identify each other and it would reduce the need for a particular conversation!” (Nate)

Different PrEP methods had an impact on participants' acceptability of PrEP based upon the dimensions discussed above. Further consideration of acceptability by PrEP method is discussed further in Chapter 8. However, a marked determinant of PrEP acceptability pertained to the efficacy of PrEP, to which this chapter now turns.

5.5 PrEP efficacy

Participants' considerations of the acceptability of daily oral PrEP were, in part, influenced by the compelling efficacy data from the iPREX trial. Given the dearth of similar data for other PrEP methods it is perhaps inevitable that participants might have viewed these other methods less favourably (although practicality of use concerns would likely remain regardless). In this section, the issue of efficacy as an acceptability dimension is explored further.

Over one third of men identified that a major acceptability factor for intermittent PrEP centered on the efficacy of such a method. That is: would intermittent PrEP offer the same protection as daily PrEP? Some men immediately translated the findings of the

iPREX trial data into potential efficacy of intermittent dosing, noting that men who had been less adherent in iPREX had been less well protected by daily PrEP.

“We already know by that [iPREX data] that it’s not very effective for people who took it badly. I think it’s the effectiveness that’s important. I think if the pills were only 50% effective then people wouldn’t be that interested in them.”
(Francis)

For some of these men, intermittent PrEP would be *more* acceptable than daily PrEP (for reason discussed above) but only if efficacy was equal or greater than daily pills.

“I’d want the one that is more likely to offer protection.” (Mattie)

Three men explored the issue of efficacy of an injectable form of PrEP. Medication administered by injections were viewed as more efficacious by one man, whilst another felt that injections were *“like a vaccine”* and so it made sense to him that they would be perceived to more efficacious. The issue of efficacy played out for Javi who considered injectable PrEP only of worth if it was as efficacious as an HIV vaccine. For him, the downside of injectable PrEP could only be balanced by a huge increase in the protection that an injection would give him.

“Only if the results were to be vaccine-like protection. If you tell me it is zero and I can go and become a cum whore then sure! LAUGHS But otherwise it would have to be ... there’s a much higher level of commitment to go to a clinic and get injected than to take a pill. It really boils down to risk. If this reduces the risk to zero or close to, then we are talking.” (Javi)

For almost a third of participants, the efficacy of longer-acting PrEP was a significant concern. Three men felt that longer-acting PrEP would have to be as efficacious, or more so, than other technologies before they would consider using it and, as with injectable PrEP, one man felt that effectiveness would need to be higher, due to the added inconvenience of having longer-acting PrEP administered or inserted. Two men, both of whom were currently taking daily medication for other health conditions, raised concerns that dosage might be insufficient if it tailed off towards the end of a three month period, or that it might have a peak and a crash. They were also concerned if an implant might work differently across individuals due to physiological differences.

“I’m not so much one for longer term because I know stuff changes ... if it has a more individual thing, like having to get the dose right, then I’m loathed around longer lasting in that sense. Like, does it last for the same time in everybody? Does it peak and crash? Those sorts of things.” (Nate)

Three men raised the vaccine-like qualities of longer-acting PrEP and Jovan saw the strengths of longer-term protection but raised his concerns that this would lead to a proliferation of other STIs as men reduced their clinic visits:

“From an HIV perspective chances are the longer the cover the better because in essence a drug can replicate the characteristics of a vaccine ... so from that point of view it’s a strength. The other point of view that this person now thinks they are impervious to STIs and they have now have three months when they don’t have to get tested. It may solve one problem and exacerbate another one.” (Jovan)

However, none of the men raised a personal concern that would increase SWC any more than any of the other potential PrEP formats. Indeed, Alex raised an interesting parallel about the protective factors and risk taking of other injectable protective medical technologies:

“[It’s] like a vaccine in a way ... um ... so it’s almost like you’re going to somewhere to prevent something. With a tetanus shot you don’t go out and start licking dirty nails because you know that you’re covered against that ... and I think that would be like the same thing.” (Alex)

For two men, the issue of the efficacy was the major dis-inhibition to topical PrEP acceptability. Whilst most men focused on the use of topical PrEP, these two men focused on both the efficacy differences between the studies on oral PrEP and topical PrEP and the potential reductions in effectiveness if gel was self-administered incorrectly. For Louis, there was a sense that topical PrEP had more potential for failure “*just in terms of the mechanics*” of how topical PrEP would be applied whilst, for Jovan, his concern included the differences due to individual physiology:

“If the pill gave a 60% greater chance of not becoming infected and the gel gave a 95% chance then it would warrant more because this gel [would then be] almost fool proof. But doing it in advance – I assume there has to be a certain amount of absorption – you can’t just suddenly start fucking like with a lube. It won’t be in the right place and it depends on the people. You know, some guys have greater anal mucus therefore absorption ... it’s certainly not cut and dry and certainly not as swallowing a pill.” (Jovan)

The bottom line for most men was: the benefit of using a method that offers the greatest protection outweighs the other costs of that method. Or, put another way: any cost of using a particular method needs to be heavily outweighed by the additional protection one would get from using it. The second most important issue was: a method with high efficacy becomes less acceptable if (one's) use of it makes it less effective. That is: if a man cannot take it, or forgets to take it; if he cannot self-administer an optimal dose (or vomits up the medication); then his acceptability of a method with a high efficacy starts to reduce. As such, it is important to factor both the efficacy and the effectiveness or usability when considering PrEP acceptability.

5.6 Negotiation and navigation

Having explored a range of PrEP acceptability dimensions for participants, the chapter now moves to consider how men might negotiate and navigate PrEP use themselves. Dimensions of personal acceptability of PrEP do not purely relate to how acceptable it is to put a drug or gel into one's body, or to be injected: the social and inter-personal dimensions of negotiating PrEP use, disclosure of use to sexual partners, and the perception of what that negotiation and navigation entails and results in, is also of prime importance in understanding PrEP acceptability. In the first sub-section, the manner in which men perceived they might negotiate their own PrEP use is explored. The section then moves on to explore how men might relate to *another* man's PrEP use and what this indicates in terms of what is, and is not, acceptable.

5.6.1 Men's own potential PrEP disclosure to sexual partners

During the interviews, men were asked to consider if they thought that they would disclose their own PrEP use to sexual partners and the circumstances within which that disclosure might occur. Over one quarter of men said that PrEP use disclosure would be something that they would consider to always or usually take place before or during sex, and would become part of their sexual negotiation or discussion – even if their sexual practice did not alter as a result of this disclosure. For these men, PrEP disclosure offered a level of *certainty* to a sexual encounter, in the same way that discussion around recency of an HIV test or a discussion around HIV status might take place. There was a sense of the normalisation of such disclosure:

“It would become part of what I already do.” (Duncan)

A further quarter of men were more ambivalent about PrEP disclosure and felt it would be dependent upon situation, circumstance and the relationship to the sexual partner. Men’s ambiguity lessened if a potential partner was regular or if they already had a level of trust established with him:

“I ... it would depend on the type of contact it was. If it was a one-off person then no. Sometimes you don’t even share your name so you wouldn’t really share more details about my personal stuff ... If it was someone I was potentially dating, or at least had a coffee or beer with or a meal or something with them first, then it might come up in conversation.” (Alex)

Some men indicated that PrEP disclosure would only arise in the context of other discussions, such as HIV status, or whether a partner with HIV had an undetectable viral load, but only in circumstances when that partner offered that information first.

“If someone offered that conversation ... someone might say ‘I have HIV and my viral load is undetectable’ and I would say ‘it’s OK, I’m also doing this’ ... so it might come up there in that sense.” (Nate)

A further quarter of men were absolutely adamant that their PrEP use would not be disclosed in a sexual context. Their reasons fell into two overlapping areas: how PrEP use would be perceived by sexual partners and issues surrounding sexual control. In the first area, Yan understood that disclosing PrEP use would indicate that men were somehow diseased, and this would put men off having sex, especially if SWC was a possibility. Interestingly, it was not unprotected sex that was seen as an issue for him, but unprotected sex *and* PrEP use.

“If you are bottom and you take PrEP ... probably your partner, they don’t want to have unprotected sex because they are afraid that they could catch something ... ” (Yan)

Of those men who would not consider PrEP use disclosure, the key issue was about being in control of their sex. Even with men who said that they were certain to discuss PrEP use with regular partners, there may be circumstances when it would not be disclosed. Max understood that PrEP use disclosure would give him a level of certainty and control in some circumstances:

“If ... and ... yeah. I would say I’m on PrEP and explain it ... and I think that would give certainty that we’ve thought about it.” (Max)

But he would construct a different strategy in circumstances when men, as he had previously discussed, tried to force SWC on him.

“What about the guys you mentioned earlier who are pushing you into having unprotected sex? Would you tell them?” (WN)

“No! No! It would give them another reason to push me. I would feel more comfortable anyway ... and either have unprotected sex with them anyway or have protected sex with them ... but I wouldn’t tell them.” (Max)

For Javi, non-disclosure of PrEP use would assist in protecting himself against risks that he found difficult to avoid:

“No. Most certainly not. Because you will be telling them that effectively I’m willing to take more risk ... It would almost be a wink and a nod to ‘yeah, yeah, you can cum in me’ which is absolutely ... no ... absolutely not.” (Javi)

Whereas Colin raised concerns that he might get coerced into not using condoms and was adamant that his own PrEP use would not be disclosed within casual settings:

“They’d have no idea if you were taking the stuff at all, so there would be no bullying you into not using a condom. You’d be much more in control. I wouldn’t tell them. No way! Absolutely no way! I would be entirely in control of my own arse and there’s no way I’d let anyone try to bully me ... No. No way! Because that is asking for trouble! You might as well get your arse in the sling at the sauna and have a ticket machine!” (Colin)

Participants’ responses to disclosure of their own PrEP use were varied, often situational and context dependent. When men presented cautious narratives about PrEP use disclosure they did so to remain in control of their sexual encounters or because of fears of how they would be perceived by others. These narratives of others’ perceptions of PrEP use are mirrored and magnified in the section that follows regarding participants’ perceptions of other men’s use of PrEP.

5.6.2 Perceptions of other men's use of PrEP

Participants were asked to consider how they would respond to a sexual partner's disclosure that he was using PrEP, if the participant himself was not using PrEP.

Understanding men's responses to *another* man's use of PrEP assists in understanding the inter-personal dimensions of PrEP acceptability, and in building further understanding of community attitudes to PrEP use.

For almost all men, this was an issue that they had not previously considered or explored and, for some men, their responses were drawn from accounts of encounters with men with diagnosed HIV, who had disclosed their HIV medication use (and an undetectable viral load) in order to negotiate sex. More broadly, men divided their responses into two narratives: one of a man seeking to guard and maintain his health and well-being by using PrEP; and one of a man who was reckless, promiscuous and not to be trusted.

For men who followed the former narrative, a partner's PrEP use – and disclosure - demonstrated a sense of responsibility and, regardless of the sex that might occur, indicated that the man was looking after his health and taking steps to avoid HIV infection. In addition, by having regular clinic appointments, such a man might therefore be less likely to have other undiagnosed STIs. Rather than being seen to be reckless, such a man was viewed as a 'good' man: a man to be trusted, and an indication that, not only was the man out to protect his own health, but was taking steps to protect the health of his sexual partners too.

“He's being responsible about his decisions. He's doing something that reduces his chance of getting HIV so that makes me safer too. That would make me see him as being more responsible, rather than less.” (Max)

“It's like the guys who quiz you in detail about when you were last tested and your status ... you know ... It would be some evidence that they look after themselves and less likely to have HIV and to pass it on to you ... so ... you know ... it would be positive to me.” (Marc)

For men who followed the latter narrative, there was a sense that disclosure of PrEP use indicated a promiscuous sexual lifestyle, with judgments being made about whether he would be a man one would want to have sex with at all.

“If you think about it ... if you ... you can think that the other person is a slut if he’s taking it ... he must be screwing around ... he might not ... but that must be one of your ideas – that the other person is quite sluttish.” (Yan)

Whilst, for other men, there was a sense of ambivalence about their response, as they weighed up a range of considerations.

“I don’t know. I really don’t know. I absolutely have ambivalence on that one. On the one hand I’m thinking ‘great, they are people that give a damn and protect’ and the other hand I’m thinking ‘they are far more likely to be going out and having bare back sex and fucking other people’, right? I’m not sure about falling between those two. Both of them ... yeah.” (Francis)

A few participants raised more fundamental questions about trust and control over HIV prevention. Philip, based on previous sexual encounters, wondered if men might disclose PrEP use, as a way of getting condom-less sex, even if they were not taking PrEP, and questioned men’s motivations for such disclosure.

“I’d look them in the eye and think ‘are you just lying to have unprotected sex with me because that is what you want? I’ve had experience of that with someone. So, I wouldn’t trust them. If they said ‘I’m taking PrEP’ then I’d be thinking ‘are they really taking PrEP?’ ” (Philip)

5.6.3 Other men’s PrEP disclosure and sexual risk

After being asked to describe their response, if any, to another man’s disclosure of PrEP use, participants were asked to consider if such disclosure would impact on the type of sex they would have with that man.

For all participants, their decisions about sexual activity and sexual risk taking, following potential PrEP disclosure from another man, were considered *alongside* their current risk taking and risk reduction strategies. Men were mindful of whom the sex might be happening with and where the sex might happen, overlaid with issues of trust and control, along with discussion about HIV risk.

Generally, as with the case of Jos, men felt that their sexual risk would not alter.

“Um ... I think ... I don’t think it would change my opinion ... I think it’s nice to know that it’s their protection from HIV ... I don’t think it would have a major

opinion of someone telling me. I'm generally having one off sex with people and I'm assuming they are doing the same thing. I guess if they are taking something like this then I guess they are saying "I have a higher proportion of sex than other men and all of that or some of that involves some kind of risk" and that's nothing different to what I should and do assume now for the people I have sex with. My risk would neither increase or decrease, no." (Jos)

Or, in the case of Javi, any increase in risk, would be tempered by his current risk reduction decisions, of not allowing sexual partners to ejaculate in him.

"Hmmm ... interesting. That's an interesting twist. I think I would be more relaxed. I still don't think I'd let them cum in me ... but I would be more willing to take a risk if they were to tell me that they are on it." (Javi)

The responses from men who said that such disclosure would be likely to have an impact can be grouped into situational or setting responses; contextual responses; and activity responses.

Situational or setting responses – these were responses that were based upon the situation or setting where PrEP disclosure took place, or where the sex was occurring. That is, for some men, the decision to permit PrEP disclosure to impact upon sexual activity was dependent on where the encounter was taking place. For Colin, this meant that the setting was crucial to his decision, not only because he could 'see' that PrEP was being taken, but based on the 'types' of men who would go to commercial sex venues.

"I think I'd make the same risk assessment that I always have. If it was in a club or a sauna then, no. If he was in my hotel room and there's the tablets by the bedside, then maybe." (Colin)

Contextual responses – these were responses based upon the context of the sex, including whether the partner was known or unknown, or if the sex was with a regular or casual partner. Generally, men were more likely to be trusting of a man they knew, and regular partners, to take PrEP, and to modify their sexual activity with him, than with an unknown or casual partner.

"Well, I say I'd be less concerned, it depends on how well I know him ... because some guys might say they are when in fact they're not." (Philip)

“I’d feel more comfortable about condoms or not condoms. If I knew a guy was taking PrEP and he was someone I knew ... then maybe perhaps ... I would ...”
(Max)

Activity responses – these were responses based on the type of sexual activity that men were describing. For men who had described risk reduction strategies, including modality of anal intercourse and ejaculation during anal intercourse, other men’s PrEP disclosure tended to sit alongside and complement those strategies.

“I probably wouldn’t bottom with him and have him cum inside me. I don’t think that would change. I might not use condoms with him if I was topping him ... that might happen.” (Alex)

“Probably not any different to how I do normally. I’d still want to use condoms. And tops are less likely to pick up HIV anyway so if he always tops then ... yeah ... it’s great he’s on the tablet but actually ... I’d still want to be safe.” (Ed)

5.7 Section Summary

In the section immediately above, participants own personal narratives of how they might negotiate and navigate PrEP use disclosure have been situated alongside narratives of how they might respond to other men’s PrEP use. It is telling that these narratives are often in conflict: although some men articulated that *other* men might perceive a participant’s PrEP use as being a sign of promiscuity (and all of the associations that go with that), far more of the participants indicated that they would consider *another* man’s PrEP to be a signal of promiscuity. That is: the social stigma and scripts that participants attached to *other* men’s PrEP use was greater than the social stigma attached to PrEP use that participants considered that *other* men would apply to *them*. This presents an interesting and challenging dynamic pertaining to inter-personal acceptability of PrEP: whilst a man might perceive that others will view his PrEP use as being broadly responsible (and acceptable), in essence, other men are likely to view that PrEP use as a greater sign of promiscuity than that individual man believes.

Overall, this chapter has explored participant’s personal acceptability of PrEP, first by exploring their *immediate* considerations of using daily oral PrEP, before going on to consider more nuanced responses to PrEP acceptability by a range of different PrEP methods. The chapter examined how efficacy of a particular PrEP method is central to men’s personal acceptability of PrEP and how men might navigate and negotiate their

own PrEP use, or that of others. The contradictions between men's perceptions of how their own PrEP use might be viewed, and how men view other men's PrEP use draw on community and societal norms around sex and sexual risk taking, to which the next chapter turns.

Chapter 6: Results - Community and societal acceptability of PrEP

The previous two results chapters focused on dimensions of acceptability that most closely align with individual perception, experience and need, or considered those dimensions that are most pressing in the context of inter-personal negotiation. This third results chapter addresses dimensions that relate to men's perceptions of broader community and societal acceptability of PrEP, and the potential impact of those perceptions on men's own personal acceptability of PrEP. That is: how community and social forces influence whether and why they consider PrEP to be acceptable to them personally.

Much has been written in the health literature about the role of peers and broader community and society on the social impact of health seeking behaviours and on attitudes to health. Bronfenbrenner's (1979) social ecological model situates the individual at the centre of the model, being influenced by community level actors and attitudes which are themselves mediated by wider social influences, all of which are interdependent. Greens and Tones (2010) further suggest that those with the most proximal relationship to an individual, including significant others and peers, have the greatest influence on that individual's health actions. Although it has been argued that more distal community or national norms (including those norms set by the media) have less impact on individual health actions, those distal norms contribute to the norms of the peer group themselves. As such, it is feasible that norms established by community peers, or by societal actors, may contribute to whether and how men consider PrEP to be acceptable. The next chapter reports on men's perceptions of broader community and societal PrEP acceptability and how both distal and proximal attitudes to PrEP might impact on men's thinking, potential use and disclosure of PrEP use.

The chapter starts with participants' perceptions of more direct or proximal influences of PrEP use, before moving on to more distal influences that might impact on PrEP acceptability. Notions of both HIV-related and gay-related stigma, and stigma surrounding sex more generally, are woven through these findings.

6.1 Discussion and disclosure of PrEP among social peers

Participants were asked to consider the circumstances in which PrEP might be discussed within social networks, and the views that social peers might have about PrEP.

Participant narratives are reported below in two overarching themes: social divisions and permissive discourse, and disclosure of PrEP use with social peers.

6.1.1 Social divisions and permissive discourse

Participants' responses to whether PrEP would be discussed with social peers were contextual and dependent upon their social circles and the extent to which they overlapped with other men's social networks. A common narrative was for men to identify a 'PrEP positive' social network and a 'PrEP averse' circle of friends. In the former group, men identified peers who they thought might personally benefit from PrEP, or would actively encourage those in their peer group to use it. These men generally tended to already include discussions about sex (and risk) in their conversations, and for these men PrEP use and discussion about PrEP would be supportive and affirming.

"I think they probably would [talk about it] yeah. I mean we're all pretty open about what we get up to and sex generally. Friends ... you know ... friends are open about their HIV status generally so ... you know. Yeah." (Marc)

These interactions tended to include men who were open about their sero-discordant relationships within certain social networks. There was a sense that men in mixed HIV status couples would openly discuss the benefits of PrEP.

"I think that most of the mixed HIV couples I know would be very enthusiastic. This is an alternative that there is to a vaccine. I think anyone in the same situation would be very enthusiastic." (Francis)

Men who identified peers who would be 'PrEP averse' talked about the potential judgment or stigma, not necessarily of taking PrEP, but for that attached to the reasons behind seeking PrEP. For these men, there was a perceived taboo about talking about unprotected sex and sexual risk with their social peers, including those peers who Alex describes as being "old fashioned" about sex. Max describes his sense of silencing about being able to discuss potential PrEP use, and the risks he takes, with some of his closest peers:

“I also have a couple of really good friends who are [HIV] positive who are slightly ... bitter is not the right word ... sort of ... really down on anyone who is unsafe. Like, if they know about the risks I have taken ... then they would be furious.” (Max)

Many of the men could identify different groups of peers who would be PrEP positive or PrEP averse and any discussion about PrEP use would be situational, depending on the peers and their perceived attitudes. It was acknowledged that, because of the relative rarity of PrEP use, peer responses to PrEP may initially be cautious, or not evidence based and that, as more men used PrEP, attitudes to disclosure of PrEP use might change.

“I would be hesitant about starting a discussion because I would just, you know, it’s like me admitting to irresponsible behaviour to friends and that would be something you are cautious about. So it would depend on the context ... but it’s possible and I can imagine that once people become familiar with it, it becomes really quite common for people to talk about it and talk about taking their PrEP pills.” (Duncan)

This notion of sex on PrEP being ‘responsible’ or ‘irresponsible’ has been a dominant feature of PrEP discourse, particularly in online environments, originating in the United States. Some stakeholders and community leaders have referred to this as ‘slut-shaming’ (Grindley, 2014): a judgment of those who openly acknowledge having a higher number of sexual partners and who take steps to protect themselves (perceived in both a positive and negative light). Louis, the only participant with experience of PrEP use, had found that some of the attitudes to sex and PrEP he had encountered online were surprising, not least because they were not views he had heard expressed within his own social networks.

“There was some judgmental comments about casual sex ... um ... which quite surprised me actually. Some conservative views on casual sex. That’s quite different from the views of people I know and mix with in London.” (Louis)

A common theme that emerged in relation to discussions amongst social peers was that failure to discuss PrEP use (and sexual risk behaviour more broadly) amongst peer networks was not seen as peculiar to PrEP, but that men (in some social circles) would not discuss any issues around sex or risk. As such, the thought of discussing PrEP was

as unimaginable as discussing HIV status, erectile dysfunction or any other issues concerning men's sexual health and, in some circumstances, would be seen as a discussion that was "going too far" (Mattie)

"Um ... I don't think there's a lot of talking about any medical issues. People are very wary of it. [The bear community] is one where there's a lot of sex happening and not a lot of talking about it, which is very bad." (Francis)

Javi went even further in describing his peer groups' discussions about sex. For him, it was not that his peers do not talk about sex at all, but that a taboo existed around discussing unprotected sex.

"I have never discussed anything like this and I don't think we would because we only tell to each other that we have safe sex." (Javi)

6.1.2 Disclosure of PrEP use with social peers

It follows, therefore, that disclosure of PrEP use within social networks is likely to be a function of the response to attitudes and discussion of PrEP or the broader sexual risk environments within those networks. As such, the signs and signals that men pick up from their peers may influence men's disclosure of PrEP use.

Participants were asked to consider the circumstances in which they might disclose or discuss PrEP use with social peers. This is an additional hypothetical scenario, but one which helps to identify how social factors may influence the manner in which conversations and decisions about PrEP may be encouraged by health professionals in the statutory and charitable sectors. Just over half of men provided a response as to whether such disclosure or discussion of PrEP would take place. Participants' responses fell broadly into three categories, and these draw parallels with the narratives men presented with regard to how they might view sexual peers' use of PrEP, as previously discussed. The first narrative presents participants as making positive health choices if they were using PrEP. Half of the men felt that they would be strong advocates of PrEP use disclosure and would actively discuss PrEP use with their social circles. For these men, they expected their friends to see PrEP use as being rational and sensible in the context of living in a high HIV prevalence city, such as London:

“My first impression is that if I was to tell my friends that I’m taking this pill and it’s halving my risk of getting infected then everyone would understand ... If I even think of my straight friends they will think that it’s a rational thing to do but then again I do tell them I’m a cum whore!” (Javi)

Here Javi highlights a key socially permissible context of PrEP use. He believes his friends recognize the extent of his risk exposure (a ‘cum whore’) and this would convince his friends to consider his decision to use PrEP as a rational one. Indeed, in some instances there was a sense that friends would be relieved to know that a man was using PrEP:

“ ... the friends I talk to about the types of sex I have, they might recommend it to me, you know ‘that weekend that’s coming up ... you know what you get like, you know, maybe you should think about that!’. Ha, ha!” (Alex)

The second narrative concerned a sense that PrEP use disclosure was not an issue for discussion, or one that would be dealt with cautiously because of the other implications of PrEP use disclosure. Two participants identified instances when men would not have a concern with PrEP use per se, but discussion would involve disclosure of a partner’s HIV status, or information a man’s partner would not want shared peers to know about, such as non-monogamy within a relationship.

The third narrative centered round an articulation that participants had a tendency not to discuss issues of any sexual nature with social peers. Of the participants who did not consider that PrEP disclosure would take place the reasons this that *“it is not their business”* (Yan) or that issues of a sexual nature – or a sexual risk taking nature – were never discussed with peers. As such, men could not imagine a circumstance when PrEP would be discussed. This issue is discussed further in the next section.

These findings illuminate how any discussion of PrEP cannot occur without an honest discussion of risk and risk-taking among gay men more broadly. Although efforts have been made to facilitate such dialogues (including by community based organisations), these efforts have rarely shown evidence of widespread success.

6.2 Societal and community influences on PrEP acceptability

Participants were given the opportunity to explore the potential social dimensions of PrEP and how existing community norms and disclosure relating to sex and risks might shape its acceptability. There are various social actors who can shape or inform the acceptability of PrEP and whose views participants took into account. These actors included social peers and broader community members; the gay media, including the more focused gay media and online media; the mainstream general media; and health professionals.

Two dominant themes emerged in men's assessments of social dimensions of PrEP acceptability: stigmatization of 'risk'; and (mis) information, norm-setting and agenda-setting.

6.2.1 Stigmatisation of risk and risk-taking

Given societal stigma attached to HIV, to sex in general and to homo-sex in particular (Fish and Karban, 2015; Pachankis et al., 2015), it is perhaps not surprising that the issue of stigma and PrEP was raised by over three-quarters of men in this study.

While few participants had encountered PrEP specific stigma, some had experienced, and made reference to, other HIV or sex based stigma. This included Roy who remarked.

"The reason my partner hasn't told anyone [about his HIV status] is because of social stigma" (Roy).

However, one quarter of men felt that there would be a strong stigma attached to PrEP use although, as has been seen with regard to men's concerns about PrEP use disclosure to social peers, these concerns around stigma were more attached to having unprotected sex, rather than PrEP use per se, or of being promiscuous.

"I'm worried ... if I was to tell someone I'd want something a bit more serious and long-term with ... it's almost like saying 'I'm slutty, whatever, I'm always having unprotected sex' and I'd worry it might be putting that person off."
(Mattie)

A larger number of men felt that stigma would not play a significant part in PrEP use, and that someone using PrEP would be regarded as sensible and, although there might be some light hearted joking or teasing, these men felt that PrEP use would not be stigmatised. A number of these men gave a caveat that this was also a reflection on *their* friendship networks and accepted that there might be broader PrEP stigma in other parts of society.

Simon felt that the potential for PrEP being stigmatised lay, in part, with the early adopters of PrEP and how these men conducted themselves, including any consequences of PrEP use – such as a population increase in annual STI incidence.

“You don’t know if these stigmas are going to develop until they do because they depend on the activities of [early PrEP users] or the people that are prominent within it and how wide flung those activities really are.” (Simon)

Mattie felt that stigma existed because, unlike being vaccinated against something that was more than 99% effective, using an HIV preventative technology that was not as effective as a vaccine might somehow carry a degree of recklessness. However, Francis’s perspective serves as a counter argument, also utilising a vaccine comparison, to make a point that he thought it irrational for PrEP use to be stigmatised:

“I don’t think in the community there would be a stigma. I don’t think I’ve ever heard someone say ‘you’ve taken the hepatitis vaccine? How horrible is that? Can you believe it? You’re such a slag!’ So no, I don’t think there would.” (Francis)

More common was a *fear* of PrEP stigma that might prevent men from discussing it.

“I know some guys wouldn’t want to talk about it. I know one guy who will be at [name of club] with things up his arse and he won’t even talk about anything to do with his arse. And I’m thinking ‘but last week I saw you with a fist up your arse and now you’re being all coquettish when someone mentions anything to do with an arse’.” (Jovan)

In addition to social contacts, a small number of participants voiced concerns about potential stigmatisation of PrEP use by medics or other health professionals. For some, such concerns were based upon their own recent experience with a sexual health professional, including Philip who had recently changed sexual health clinics because

firstly he considered he would be viewed as ‘bad’ by the clinic staff, and secondly because he had been pressured into attending counseling services that he considered he did not require and did not desire. This, coupled with an unwillingness to have his HIV prevention ‘controlled’ by health professionals, led him to conclude that his own experience of medical professionals would make PrEP less acceptable.

Jovan also raised a concern that men’s internalised views of what it was to have an STI or to have SWC would make it hard to honestly convey personal sexual behavior to medical staff, and thus be in a position to access PrEP.

“I think a lot of men when they get tested are afraid to be honest and tell they have been a dirty whore because a lot of people internalize that and they think ‘I am a bad person, I really am a whore. I am not in the hetero normative, you know, finding a partner and settling down’. And they won’t want to admit that to their friends, let alone a clinician.” (Jovan)

In reality, concerns about PrEP acceptability from medical staff were raised by only a small number of men. With one exception, articulated concerns were based on men’s perceptions of how they might be treated or judged, rather than prior experience of an unsympathetic service. That said, such perspectives highlight an important concern that future PrEP providers articulate clearly and publically their non-judgmental and supportive PrEP based services.

6.2.2 Mis-information, norm setting and agenda setting

Two men reported that they had seen comments about PrEP on web-based gay media forums and raised concerns that misinformation about PrEP, and attitudes or opinion about it, rather than facts or evidence would influence whether *other* men consider PrEP to be acceptable. Louis voiced a concern that the gay media gave a correct and evidence-informed analysis and reporting about PrEP and its potential to reduce HIV.

“In terms of the gay media, rather than the mainstream media, who will have a field day whatever, I find it really hard to imagine them as not recognizing [PrEP] as the third way. I don’t really care what people think ... I don’t really care if [name of magazine] says ‘PrEP’s not effective enough’ [but] I care that people will make decisions based on that.” (Louis)

However, as was seen in Chapter 4, although some participants had heard about PrEP through community internet channels, none of the participants demonstrated that their views on PrEP had been shaped by misinformation.

A similar view was articulated by a small number of men with regard to how the broader (mainstream) media might view and report on PrEP. This was especially the case given the media's potential role in societal norm setting and in setting public health policy agendas. Of those men who raised concerns about how the media might impact on PrEP acceptability, concerns were far less about potential PrEP stigmatisation and much more about how (mis) reporting of PrEP might impact upon a policy setting agenda, and therefore PrEP availability on the NHS.

“I’m really concerned about negative spin in the press. In my head I have a transmission curve ... and it just becomes exponential. As a scientist you can see the value of that. And as someone reading the Daily Mail you can’t. These things really concern me because we need ... a third option. Whether PrEP is a little bit effective or a lot effective we still need it ... and that worries me.”
(Louis)

Despite participant's narratives that broader media coverage of PrEP would be unlikely to have an impact on personal acceptability of PrEP, it is worth emphasizing how media can shape norms more broadly. As such, negative media portrayals or narratives of MSM using PrEP to enable or facilitate doing 'risky' activities has the potential to have a significant consequence for how information about PrEP is disseminated at a population level.

6.3 Summary

Few men felt that societal or community attitudes to PrEP would personally impact or influence the acceptability of PrEP for them. Most men felt they had a strong element of personal resilience and that PrEP acceptability was largely influenced by other factors (including those explored in Chapters 4 and 5) and, if they had made a decision to access PrEP, the attitude of others – especially 'others' who they did not know – would have little impact or influence.

There was a broader concern about misinformation or the influence of the media in shifting the landscape of PrEP – especially for men who had not heard about PrEP

through other sources. Although community or societal views of PrEP were seen to be unlikely to impact on men's personal use of PrEP, those norms were seen – for some men - to impact upon if and how men discussed PrEP use with their sexual peers. The implications of this are considered in the discussion.

Chapter 7: Naivety, certainty and ambivalence: four case studies of PrEP acceptability

The aim of the following brief case studies is to provide a holistic sense of the acceptability and potential for PrEP use among four of the study's participants. Each case study builds on the data previously presented in the results section. They highlight the dynamic nature of individual's PrEP beliefs, including their own inconsistencies in how PrEP might be used or considered. These case studies are presented as data from individual participants and are not composite narratives from several men. The process of qualitative analysis can fragment the nature of human perception and experience. In breaking down the speech of individual's line-by-line and re-constructing as themes, alongside other people, something of the gestalt is lost. These case studies are presented as a way of counter-balancing that and present, in a more holistic way, individual thoughts and feelings relating to PrEP and its acceptability.

As discussed in Chapter 3, given the nature of applied research within a DrPH, that embeds the transferability of research into practice and policy, these case studies are also intended to provide an over-arching summary of the broad perspectives of participants in a way that is more relevant and accessible for non-academic audiences.

These four men were selected as case studies as they provided the most distinct characterisations of PrEP acceptability and potential use: the naïve risk taker, for whom PrEP would not be deemed acceptable as the man could not recognise his HIV risk; the man who definitely would seek PrEP; the ambivalent man, for whom PrEP would be acceptable in certain circumstances but had a considered approach to determining PrEP use; and the man who would not use PrEP, broadly for whom HIV risk was deemed insufficient to warrant PrEP.

Although all other sixteen participants fell somewhere into these categories, most fell somewhere across one or more, with sometimes more complex narratives surrounding risk, sex and potential PrEP use than those more easily categorised above.

7.1 Simon: the naïve risk taker

Simon, one of the youngest participants in the study was the most obvious naïve risk taker within the study. It might be tempting to ascribe his naïve risk taking to his youth, yet elements of naïve risk taking can be found in other participants, including men almost twice Simon's age.

Simon described how he regularly attended bars in one of London's gay neighbourhoods where, after a few drinks with friends, he would start to look for men nearby on his phone. Almost all of Simon's sex was unplanned, with the majority of encounters occurring using phone apps and to meet an immediate sexual need, rather than to pre-plan ahead for sex. HIV testing occurred periodically, based on the numbers of men sex had occurred with, rather than the types of sex that have taken place. Although some unprotected sex was pre-planned with someone he knew or had already had an encounter with, most of the "*immediate quick fix*" sex was without condoms. He rarely talked to men about HIV status before or after those quick encounters and rarely employed other risk reduction strategies, although sometimes considered not letting a man cum inside him but as he said, "*Yeah, I might. It's that key word – might!*". Simon believed that it was unlikely that he had had unprotected sex with someone with HIV:

"Yeah, as far as I'm aware ... conclusively ... I have not had sex with someone who is positive".

He said that if a man told him he was HIV positive then sex would be unlikely to happen or continue:

"I think ... god ... I suppose if someone says that they are positive ... it will ... not bring your back up ... but bring things to your forefront. Being brutally honest I don't know, especially on a one-night stand, that I would sleep with someone if they were positive. Um ... which probably sounds very harsh ... My shut-down mechanism would be just to shut it down".

Whilst Simon's sexual risk taking might make him an apparent candidate for PrEP, he held strong ambivalence about considering PrEP. For him, the issues of remembering to take a pill on a daily basis would be challenging, and he would need more consideration of longer-term side effects. Intermittent oral PrEP and topical PrEP sat less well with the more spontaneous nature of his sex planning and although injectable PrEP offered

some level of acceptability, Simon wanted to know more about those technologies and their use in the real world before better determining their acceptability. Although he raised a potential concern about his own sexual risk taking increasing as a result of using PrEP, he remained fairly adamant that he would still not have sex with a known HIV positive partner whilst using PrEP.

7.2 Martin: the definitely wants to use PrEP

Simon's understanding and conceptualisation of risk contrasted sharply with that of Martin, whose risk taking was far more cognisant. Martin was in a non-monogamous relationship with a partner with HIV and an undetectable viral load. They had unprotected sex together, with Martin being the receptive partner and with ejaculation often occurring. As such, Martin considered that *"it is responsible for me to test regularly"*. Martin went through a lengthy and informed process with his partner to decide not to use condoms, seeking advice from HIV positive peers and health professionals. Martin had other regular partners with whom unprotected sex was almost always planned and negotiated. Condoms were used during anonymous intercourse, such as in a sex venue, and Martin concluded that his sex was *"not some sort of a reckless stab in the dark mistaken behaviour ... it's pretty well informed"*.

On hearing about the results of the iPREX study when they were first released, Martin attempted to access PrEP but was told that NHS guidelines prohibited his doctor from prescribing them. As such, if a daily PrEP pill became available in England, Martin would want to start using them. Minor and manageable side effects and clinic visits would be an expected part of taking such a medicine.

Other forms of oral PrEP and topical PrEP were seen as less acceptable as they required pre-planning of sex. Although a rectal gel was seen as a possible option for the future, issues around application and messiness made it far less acceptable. When considering injectable formulations of PrEP, injections made it less likely that a pill would be forgotten to be taken, but the biggest factor of acceptability was the effectiveness of any method:

"You know ... if a certain format of medication is more effective than one another, then that is the one that should be used. I don't particularly think that

the way that it's given is not necessarily ... I mean it wouldn't be the deciding factor for me. I would take the most effective ... I'd prefer the most effective format rather than the one that gave me the most comfort, if you like".

Martin saw that taking PrEP would broadly be seen as acceptable within a large part of his social circle, particularly those in which sex was already discussed and that PrEP use would not be something he would be ashamed of. Rather he would see it as “*a mechanism for on-going health*”.

Given Martin's consideration of how he managed sexual risk, it is no surprise that his response to the possible impact of PrEP use on sexual risk was as equally considered. In some circumstances, PrEP use might change the type of sex that would be negotiated and take place; for example if a man with HIV had a detectable viral load. In these circumstances, Martin clarified that:

“I would be more comfortable having condom less sex with him ... It doesn't mean I'd definitely have condom less sex with him but I'd feel more comfortable if that was the case”.

7.3 Alex: the ambivalent

Alex provided a much more ambivalent narrative to PrEP use. He reported that his patterns of seeking sex had changed over recent years, with far less focus on quick sex. With a previous partner where condom use was stopped during the duration of the relationship, Alex usually otherwise used condoms during sex. During recent encounters he had had a number of unsafe experiences to which he accounted as being due to being drunk, having used recreational drugs and having low self-esteem. He reported:

“The combination of those three things kind of made me more careless. I was going to say carefree but that has the wrong connotations. Yes ... more careless ... to not paying enough attention to what I was doing, as to what I should be ...”.

One of his risk reduction strategies was to attempt to ensure that those three risk factors did not collide: something that he accepted is a challenge given that one way of escaping from low self-esteem or depression is to self-medicate with drink or drugs.

Having read about PrEP briefly in a news article, Alex was keen to understand more, including about possible side effects and the impact of not remembering to take pills regularly. If he were in a sero-discordant relationship then Alex's acceptability of personal PrEP use was clear: it would be something that he would be very interested in taking.

"If there was a reason to take it because your partner is HIV positive and you're not, then I think that would be more of ... more of an impulse ... you know. More of a driving factor to make sure you take it as you should."

But as a single man, even one having occasional and irregular SWC with men whose HIV status was unknown or not discussed, Alex's PrEP use became more ambivalent. He raised a concern that PrEP use might potentially increase his sexual risk taking and then articulated that taking a daily pill might serve as a reminder to why he would be taking the medication in the first place, and that might further modify his (safe) behavior:

"Actually, probably strangely ... by taking a daily pill it's kind of a reminding you of what's at risk. I think if that was a constant reminder every day – I have to take the pill, I have to take the pill – it might click in if you were getting in to a situation and you'd think 'hang on a second, there's a reason why I'm taking this ... there's a reason why this behavior might be risky so let's do something about it."

Both intermittent oral PrEP and injectable PrEP were viewed as being more acceptable than a daily oral pill – not only because Alex could see the former better fitting his lifestyle but because he associated pill taking with being ill. Yet, he saw an injection as being more like an inoculation:

"It's something to do with the psychology behind it: it's less worrisome but still providing the same benefit maybe."

For Alex, injectable PrEP provided a different analysis of sexual risk compared with oral PrEP in that he articulated that injections, which he saw as being similar to vaccines, would be less likely to lead to sexual risk.

7.4 Ed: the would not use PrEP

Ed, another of the younger participants in the study, typified the view of the quarter of the men in the study who would not find PrEP use personally acceptable. As has been discussed, the two primary reasons for not considering PrEP personally was a concern about putting drugs in to one's body and not considering one's HIV risk to be sufficient to take PrEP. Ed straddled both of those reasons.

Ed used clubs and bars and other social venues as a setting for meeting men for sex and although Ed was also a user of smart phone apps, he rarely met men for instant sex, preferring rather to pre-plan and arrange to meet a potential sexual partner in a venue.

He was a regular tester, regardless of the type of sex he has had, and had few encounters that involve unprotected sex. His most recent one was with a man *"and basically we were just playing around and he sat on me and it was sort of not for very long because after a moment I kind of was ... right ... like no ... actually."* Other encounters had almost exclusively been with condoms apart from an occasion of condom failure and non-condom use during monogamous relationships.

Ed raised a personal conflict concerning PrEP in that he could see the benefits of it in preventing HIV but felt that it was fraught with potential danger if *"it's encouraging risky behaviour"*. The friends he had discussed PrEP with shared this view.

If Ed were hypothetically using PrEP it would not alter the sex he was having. He would disclose his PrEP use to sexual partners but would not let this be seen as permission to them not to use condoms. If another man disclosed his own PrEP use then sex would *"probably not be any different to how I do normally. I'd still want him to use condoms."*

Ed's unambiguous statement of a desire not to use PrEP was based primarily on his perceptions of his lack of HIV exposure risk:

"I guess there's always an element of chance but I wouldn't really feel comfortable taking something when it isn't really something I need ... I like to try to be safe ... I know it's preventing something but I can use these other

methods, although they aren't completely [reliable] then I'd rather stick to them I think."

This was enhanced by a consideration of the possible side effects and toxicity of PrEP and seeing himself as *"not really a big drug person and I don't really like to take drugs unless I need to"*.

If Ed, again hypothetically, took PrEP, intermittent oral PrEP would be preferable to daily oral PrEP: not only did he consider the toxicity and side effects to be less, but he understood that such a PrEP method might fit more neatly with how he pre-plans sex.

7.5 Summary

As outlined in Chapter 3, these case studies serve to provide a more holistic concept of PrEP acceptability, sitting alongside the more thematic results section in the preceding three chapters. They further serve as more easily digestible overviews of four key accounts of PrEP use, especially accessible for non-academic readers, policy makers and health promoters.

In the following chapter, the results from the preceding four chapters are synthesized and discussed.

Chapter 8: Discussion

Introduction

This research set out to explore the acceptability of HIV PrEP among MSM in London. It adopted a holistic approach to the consideration of acceptability, recognising the personal, inter-personal, social and community dimensions that influence or inform whether or not something is acceptable. A qualitative methodology, that employed in-depth interviews with twenty MSM in London, was considered the most appropriate approach, given the multiple and discursive elements of acceptability and the need to understand individual perceptions and consideration of PrEP.

In the preceding results chapters, data were presented from these interviews with men who, given their self-reported prior risk behaviour, potentially stood to benefit from greater availability and use of PrEP. Those chapters explored the acceptability of PrEP from the positions of the personal, inter-personal, community and societal, acknowledging that each dimension has a role in uptake and efficient use by the individual. In this discussion chapter, I draw together these strands to consider the acceptability of PrEP among this sample of MSM, and contrast these findings with other contemporary evidence relating to PrEP. The chapter establishes the key findings of the research before moving on to explore in further detail how this thesis adds a unique contribution to the evidence base on PrEP and its acceptability. The discussion focuses on major findings from the research and the chapter concludes with discussion on a proposed model for improving our understanding of how PrEP acceptability amongst MSM might be better articulated and understood in future research and health promotion practice.

As is acknowledged throughout this thesis, the evidence relating to PrEP uptake and use, as well as the policy environment of provision is developing apace and, as such, this discussion chapter discusses emerging evidence that was only in development when field work for this thesis was being undertaken. The discussion chapter places particular emphasis on areas where emerging evidence is compounding and where recent published evidence serves to further develop the findings described in this thesis.

8.1 Key findings of the research

In this first section the key findings from the thesis are outlined and summarised. These key findings form the basis for the discussion in the following sections of this chapter and for the conclusions that follow in chapter 9. The key findings of the research are:

- Daily oral PrEP was broadly personally acceptable to this sample of MSM living in London who are exposed or potentially exposed to HIV. When PrEP is personally unacceptable, it is generally so because men consider their HIV risks to be too insignificant to justify using a daily pill, because they were concerned about the possible side effects, or because they are uncomfortable using a pharmaceutical medicine to prevent HIV.
- PrEP was most acceptable to those men who knew they were taking the greatest risks of contracting HIV, and when men have a close proximity to HIV. Men who were less cognisant of the risks they were taking that might lead to HIV transmission, or did not consider themselves to have a close proximity to HIV, were least likely to consider PrEP use personally.
- Participants positioned PrEP as having benefits that move beyond HIV prevention. These benefits included the ability to increase intimacy, pleasure and opportunity during sex, and to reduce the stress that surrounds sex. This was particularly the case for men who had a primary HIV positive partner or sero-discordant relationship.
- The extent to which different methods of PrEP delivery were considered acceptable varied. Intermittent oral PrEP was attractive to men who felt their risks did not justify taking a daily pill. However, methods that require pre-planning of sex were felt to pose particular challenges in a world when sex is increasingly spontaneous.
- PrEP became more acceptable when viewed as a range of technologies and methods that include, but are not restricted to only, daily oral PrEP. Participants who were taking, or who had sought PrEP, found methods other than daily oral PrEP to be more acceptable than men who had never taken or sought PrEP,

suggesting a continuum of acceptability and the role of prior personal experience in informing this.

- Although there were some dimensions of acceptability that differ according to different PrEP method, the biggest determining factor was efficacy of the method. Men felt they might be willing to experience more inconvenience, or greater discomfort, for example, if a particular PrEP method offered them greater protection than another method.
- Participants broadly viewed PrEP as an HIV prevention method that could be incorporated with and used alongside their existing HIV risk reduction strategies. Whilst some men considered that the sex they have without condoms would increase if they used PrEP, most men's narratives on PrEP and sexual risk were considered and cautious.
- Broadly, men's decisions to discuss and disclose their own PrEP use, should they decide to use it, mirrored the discussions and disclosure that surrounds their current sexual activity. Control was central to men's considerations of PrEP discussion and disclosure and participants could identify occasions and situations when PrEP use disclosure could diminish and strengthen control over their sex.
- Despite participant's own views on PrEP use and PrEP use disclosure, participants' views on *other* men's PrEP use cast challenges and contradictions about how men might view PrEP use by others. Although some participants viewed other men's PrEP use as being rational and a signal that a man looks after his health, another strong narrative emerged that positions other PrEP users as being promiscuous and therefore men to be avoided.
- Decisions to discuss PrEP, and its use, with social peers, also mirrored the discussions that took place regarding sexual activity. When participants said they do not discuss other sexual issues with social peers, then they also said that PrEP would also be unlikely to be discussed. Conversely, when men had

relationships with social peers where HIV, sex or sexual risk is discussed, then discussion about PrEP and its use was seen to be more amenable.

- Participants recognised the role that community and social actors have in influencing the discourse on, and attitudes to, PrEP. Whilst stigma about PrEP featured as a major theme in men’s narratives of PrEP use, the overwhelming majority of participants determined that stigma about PrEP would not deter them from seeking or using PrEP. However, stigma or perceptions of a negative response from social peers, or other social actors, would contribute to how and whether men would discuss or disclose their PrEP use, including in sexual situations.
- Participants’ major concern relating to community and social actors was the ability of such actors to dictate or wrongly influence public agenda setting on PrEP, including publishing misinformation about PrEP that might deter other men from seeking it.

8.2 Willingness to use PrEP: contributors and barriers

The second objective of this thesis focuses on understanding men’s willingness to use PrEP and the contributors and barriers to that potential use. This section examines a number of key themes, drawn together from across the preceding chapters that relate to willingness to use, and overarching acceptability of PrEP. I begin with a discussion of perceptions of risk and the notion of naïve risk taking, which is central to discourse regarding PrEP among this sample. This is followed by a consideration of the wider, holistic health benefits of using PrEP, and the level of health systems engagement that would be required. As has been the case throughout the history of the HIV global pandemic, Chapter 6 illustrated how perceived or felt stigma plays a role in how men consider PrEP (and how they may discuss it) and this is further reflected in this section. Finally, I examine men’s perception of how PrEP could be integrated into their sexual lives alongside their existing HIV risk reduction strategies. The ease of use, or of integration, was central to some in how they considered PrEP acceptable, or otherwise.

8.2.1 Risk perception and naïve risk taking

Whether or not men considered themselves at personal risk of contracting HIV, or other STIs, significantly influenced their perception of PrEP and whether or not they considered it acceptable. In short, those who did not perceive a high risk of HIV acquisition were less likely to be personally willing to use it, and found the concept in general less acceptable. However, as described in detail in Chapter 5 (as well as in case study 7.1), a small number of men in the study presented a risk analysis that was flawed or naïve. As with the case of Simon, his unwillingness to consider using PrEP was based on his assumption that the SWC he was having was primarily HIV sero-concordant and he struggled to conceive of a scenario in which he had had sex with someone who had HIV, now or in the future. In the context of an active sexual life in central London, with a HIV prevalence of nearly 1 in 8 MSM (Yin et al., 2014), this is – on a subjective level – somewhat naïve. Other men presented scenarios where a justification or rationalisation was made about the sero-status of partners (such as based on the setting in which sex occurred), and failed to take account of the challenges that some men with diagnosed HIV experience in disclosing their status. As reported in Bourne et al (2015), some gay men with HIV rely on behavioral indicators of their status (such as the sexual position they adopt or the type of sex they have), which can stand in conflict to the assumptions that HIV negative gay men can hold about the likelihood of a HIV positive man actively disclosing (i.e. the assumptions that positive and negative men make about the nature of disclosure are not always in sync).

Such naïve risk taking has presented challenges for HIV health promotion for decades (Henderson et al., 2001; Keogh, 2007; Reid et al., 2002; Williamson et al., 2008) and the advent of PrEP illuminates these challenges, and the contradictions of naïve risk takers, further. For, not only might a naïve risk taker be unwittingly exposing himself to HIV, he might (based on the assumption that the men he has previously had sex with must also be uninfected) pass on HIV to other sexual partners at an early stage of infection and when most infectious, based on his own assumption that he is uninfected.

This is the first research that attempts to draw out the implications of such naïve risk taking within the context of PrEP provision and access. If PrEP is going to realise a significant public health (rather than solely an individual) impact, such naïve risk takers need to be at the centre of frameworks that engage MSM about PrEP. It is likely to take

a significant number of men cognisant of their exposure to risk to be using PrEP to provide a notion of “herd-immunity” to HIV for men such as Simon. Indeed, understanding that some of the men who shun those who disclose a HIV positive status are also likely to reject men who disclose their PrEP use (as discussed further below), it is conceivable that men who base their risk reduction strategies by seeking “neg for neg only” will be taking even greater, not fewer, naïve risks. In this scenario, men will be rejecting those with undetectable viral loads or those whose PrEP use means they cannot have undiagnosed HIV.

However, it is important to also consider the broader consequences of risk perception and how this could impact PrEP access or uptake. The fact that men who perceive only a limited likelihood of HIV exposure consider PrEP to be less acceptable has an obvious impact on the cost-efficiency of this intervention (i.e. at a general level, those less at risk are less likely to want to use PrEP). This finding is in line with those reported in the iPREX OLE study (Grant, 2014) where participants most willing to continue to participate in the study were those taking the greatest HIV related risk. Those who considered their risk to be insufficient to justify taking PrEP were more likely to stop taking it in this open label trial. However, I return to the notion that self-assessment of risk exposure is problematic, and these potential outcomes have to be considered accordingly.

8.2.2 Holistic dimensions of health and well-being

Although PrEP is broadly conceived and conceptualised as a technology that would be most beneficial to those taking the greatest HIV risk, this study establishes that there may be additional, more holistic health benefits afforded by PrEP that influence perceived acceptability. In a bid to capitalise on the public health impact of PrEP, discussions on who should be offered PrEP, and in what circumstances, have focused on those most likely to acquire HIV within certain prescribing guidelines (NHS England, 2015). For example, suggestions have been made that HIV negative partners of men with HIV who have an undetectable viral load (and are therefore unlikely to pass on HIV), would not additionally benefit from using PrEP (as the ‘extra’ protection that PrEP would offer would be negligible) (Pebody, 2015).

However, findings articulated in this thesis demonstrate that men understand the benefits of PrEP to be more complex and holistic than purely an HIV prevention benefit. This study highlights that some men in sero-discordant relationships consider that PrEP offers the opportunity to share the responsibility of HIV prevention with their HIV positive partners, and that potential could be seen for a greater level of intimacy and pleasure within such relationships. Other participants recounted that PrEP might offer the opportunity to have intimate, longer-term relationships with men with HIV, or that using PrEP might lead to a reduction in stress or anxiety during or after sex, even if SWC occurred infrequently.

These more holistic dimensions of PrEP acceptability identified in this research offer challenges and opportunities for future PrEP provision and broader sexual health promotion amongst MSM in England. The most obvious challenge will be to situate these dimensions within NHS prescribing criteria: criteria that currently seek to demonstrate that the broad prescribing of PrEP will be cost-effective or cost saving to the NHS (Cambiano, 2015; Ong et al., 2015). A further challenge is that men who do not fit any future prescribing criteria but who might benefit from PrEP more holistically, might be those who can either most afford to purchase PrEP privately, or who have sufficient social capital to access PrEP in other ways (including knowing how to navigate, albeit dishonestly, an NHS prescribing system), further exacerbating sexual health inequalities (EMIS, 2013).

The most obvious opportunity might be to diminish fear and anxiety and to increase intimacy and pleasure during sex by prescribing PrEP. However, those presenting to NHS services with a low HIV exposure risk but with other anxieties and concerns about sexual health or HIV offer the biggest *additional* opportunity of PrEP (other than preventing HIV): by situating PrEP services within a broader (sexual) health service that offers a range of interventions and services that address a broad range of (sexual) health needs, even when a desire to access PrEP is a man's presenting issue. So, for example, a man attempting to access PrEP because of concerns about maintaining erections when condoms are used, might better benefit from an erectile dysfunction service, and be referred to such a service – a service he might otherwise have been unwilling to access independently. Just as men in the study saw the STI and sexual health opportunities of having a regular PrEP clinic visit, attempting to access PrEP –

even if the underlying (sexual) health issue might be better resolved by an intervention other than PrEP – offers huge opportunities for improving MSM’s more holistic health and well-being.

Despite the fact that there were clear perceived benefits of using PrEP, these were sometimes counter-balanced by other concerns that had the potential to negatively influence health and wellbeing. As was reported in Chapter 4, men who were not keen on taking PrEP can be broadly divided into two groups: men who fundamentally disagree or object to taking medication (for preventing HIV), and men who do not believe that their risk taking justifies taking PrEP. For this first group, reasons include concerns about side effects or of following a pill-taking regime. Two-thirds of participants expressed a concern about potential side effects of PrEP (sometimes associating side effects with experience of using PEP), although many men understood that the potential time-limited nature of side effects would not negatively impact on their actual use of PrEP. This finding mirrors much international evidence that concerns about side effects may serve as a barrier to PrEP uptake, yet these concerns have broadly shown to be misplaced (Grant, 2014; McCormack et al., 2015) and points to the need for UK health promotion on PrEP to address this potential barrier to uptake.

8.2.3 PrEP use and stigma

One quarter of men felt that there would be a strong stigma attached to using PrEP – although these concerns about stigma were more attached to PrEP’s associations with unprotected sex, or of promiscuity, rather than PrEP per se. However, more than half of men felt that stigma from friends and their wider community would not play a significant part in any decision to use PrEP – although men accepted that this might be a reflection on their peer networks and accepted that stigma might exist, and play a part, for other men.

Given the discourse on stigma around PrEP use, much of it appearing from within the USA (Garner, 2012; Glavek, 2013; Stangl et al., 2012; Highleyman, 2014; Stern, 2014b), it could be considered surprising that men in this study did not consider potential stigma around PrEP use as a more prominent factor influencing their overarching perception. It could be that, as PrEP use becomes more prevalent in England and Europe, the playing-out of more stigmatising discourse will grow. Whilst

men broadly reported that they did not expect stigma or anti-PrEP attitudes of peers, health service providers or the media to have an impact on their PrEP seeking behavior, there was a clear indication that stigma or fear of judgment (either about using PrEP or about what might be associated with PrEP use) might prevent men from discussing PrEP with peers or health service providers, or from disclosing PrEP use with sexual partners. As such, the potential stigma associated with PrEP stands to have an impact on one of the most powerful ways that gay men have traditionally sought information and support about sex, sexual health and HIV prevention: directly from their social and sexual peers. The potential silencing of discussion and disclosure of PrEP use due to stigma carries parallels with the silencing of those with diagnosed HIV (Bourne et al., 2012).

It is useful to situate these concepts of PrEP related stigma within broader theories of HIV related stigma. Stangl et al (2012) provide a framework for conceptualising HIV stigma and discrimination in which these data can be positioned. Stangl's framework provides conceptual domains for understanding (and measuring) stigma that might also be applied to PrEP stigma that include: anticipated stigma (fear of consequences of PrEP use and its disclosure); perceived stigma (such as perceptions of how others will view PrEP users); internalised stigma (acceptance of negative feelings associated with PrEP use or SWC); and experienced stigma (actual experience of discrimination associated with PrEP use, for example). The strength of positioning PrEP related stigma within Stangl's framework is that the framework identifies the drivers of stigma and where to intervene. By indicating how stigma functions, it is possible to identify where to intervene: providing a framework for action for HIV (and PrEP) health promoters (see related recommendations in Chapter 9).

8.2.4 Incorporating PrEP into current risk reduction strategies

In some respects, one of the key factors that influenced the extent to which participants considered PrEP to be acceptable was that most perceived it easy to integrate alongside their existing HIV risk reduction strategies. One of the most commonly voiced concerns about PrEP has been that PrEP use will lead to population wide reductions in condom use (Evans and van Gorder, 2013; Heywood, 2014; Highleyman, 2013). Despite findings from a range of international research that consider this not to be the case,

recent high profile media commentary has fuelled these concerns further (Peterson, 2014; Stern, 2014).

However, despite participants being asked about their hypothetical sexual activity in the future, should they use PrEP, nearly all men felt that PrEP would be used in conjunction with and alongside their current risk reduction strategies. It was perceived as an additional strategy that could complement their current strategies including decisions about internal ejaculation, modality of anal intercourse, discussions around HIV status and recent HIV testing history, and condom use, rather than replacing these strategies altogether.

How men would respond to PrEP use reported by sexual partners was felt to be dependent on where the encounter was taking place, the context of the sex, including if the man was a casual or regular partner; and the type of sexual activity that was taking place. These considerations were overlaid with issues around trust, and being in control of sex and sexual risks, which it was felt personal PrEP use could help to develop. In turn, men's considerations about disclosure of their own PrEP use fell into three areas (with equal numbers of men in each group): the first said that disclosure of their own PrEP use would be something that would always or usually take place as part of sexual negotiation and discussion – even if sexual practice did not alter as a result of this discussion; the second group of men were more ambivalent about PrEP disclosure and it would be dependent upon situation, circumstance and relationship to a partner; and the third group were adamant that PrEP use disclosure would not take place – either because of how they thought they would be perceived by sexual partners or because of issues of sexual control.

These accounts have obvious implications for how PrEP educational and awareness interventions may be implemented, given that men's risk reduction strategies may already be complex. Accordingly, if and how men disclose or negotiate sex when using PrEP has implications for non-PrEP users, including those with diagnosed HIV. Men's accounts of *other* men's PrEP use also gives us some (albeit limited) insight into how HIV negative men who have regular or occasional sex might negotiate sex with other men who are using PrEP. Central to these narratives are issues of trust, honesty and who

is in control of men's HIV prevention: narratives that resonate with negative men's accounts of 'trusting' another man's recent negative HIV test results, or that a man with HIV really has an undetectable viral load when he reports that he has.

8.3 The relative acceptability of different PrEP methods

In Chapter 6 the differences in participants' acceptability of PrEP were distinguished according to different PrEP methods. Although PrEP efficacy was generally constructed as the central component of personal PrEP acceptability, the differences of acceptability by method are worthy of further discussion. As such, this section addresses the third objective of this research – the relative acceptability of different PrEP methods.

8.3.1 Daily oral PrEP

When fieldwork commenced for this research, daily oral PrEP was the only PrEP method for which efficacy data for MSM existed. As such, it might be expected that daily oral PrEP would be viewed more favourably than any other PrEP method, and broadly, it was seen by participants to be the PrEP method they would most likely to consider. Since field work, further evidence has galvanised the case for daily PrEP (Grant, 2014; McCormack et al., 2015) evidence on the efficacy of daily oral PrEP remains the most compelling aspect of its acceptability to MSM in London. In addition, far more MSM are now using daily oral PrEP than when fieldwork commenced through clinical trials (anecdotal estimates suggest that around 400 of the PROUD participants continue on the trial since the closure of the deferred arm) and through self-purchase or private prescription. As such, more men will be now more familiar with concepts of daily oral PrEP and it makes sense that this familiarity might lead to a greater level of acceptability, as more men start to experience using PrEP, or discussing its use.

8.3.2 Intermittent oral PrEP

At the point of fieldwork for this research, intermittent oral PrEP remained a concept for which evidence was lacking. Since completion of fieldwork, and as highlighted in Chapter 2, a broad range of evidence, not least from Ipergay, exists on the feasibility of non-daily PrEP. This includes event-based dosing (taking PrEP before, and then after intercourse) and time-based dosing (taking PrEP a certain number of times a week – but not daily – and then a short time after intercourse).

A key finding from this study was that participants saw three key benefits of intermittent PrEP, compared with daily oral PrEP: first, that they might experience fewer side effects; second, if PrEP had to be purchased it would cost less to take a pill intermittently rather than daily; and third, it was viewed as a more suitable option for men whose sexual risk taking occurs only occasionally. These findings are consistent with other recent studies into intermittent PrEP dosing (Molina, 2015) and help to build a picture of PrEP being used in two, possibly overlapping, ways: first, daily oral PrEP being used by MSM who take on-going and regular risks; and second, intermittent PrEP being used by men whose (risky) sex is less frequent, occasional and planned (and when men do not find the possible side effects of *daily* PrEP acceptable). The study identified situations when participants could see the benefits of following one regime and then switching to another: an approach that reflects what is commonly being referred to as men's 'seasons of risk' (Newman, 2015a). The ability to switch between different types of PrEP dosing regimens will offer potential challenges to PrEP educational activity and again underlines the possible complexities of the prescription and administration of PrEP.

As was explored in section 5.5, efficacy of PrEP was the biggest issue of acceptability by different PrEP method and over one-third of men stated that this would be of similar concern to them with regard to intermittent PrEP. It is worth reflecting back to the data from the iPREX study that suggested that non-daily dosing of PrEP offered significantly less protection in that trial. These concerns are partially compounded by more recently published research. Despite the findings from Ipergay, and evidence from iPREX OLE, that four or more pills a week are sufficient to be protective (Grant, 2014; Molina, 2015), efficacy evidence on non-daily oral PrEP still remains less compelling than that for daily oral PrEP. Indeed, the authors of the ADAPT study (a phase II open label study of Truvada based in Bangkok, Cape Town and Harlem, New York) note that "non-daily dosing is feasible ... if someday it is proven to be effective" (my emphasis) (Amico, 2015; Chemnasiri, 2015; Franks, 2015) and other commentators (Collins, 2015) have called into question the evidence base of some recent prescribing decisions concerning non-daily PrEP. As such, further evidence on the efficacy of non-daily PrEP compared with daily oral PrEP is necessary if it is to become a compelling alternative.

Even if efficacy data for non-daily PrEP could be better demonstrated, intermittent PrEP dosing would still remain unacceptable for some men because of a central issue relating to effectiveness: remembering to take a pill that is not taken on a daily basis. This finding is further illuminated by the recent release of the Phase 2 HPTN 067 ADAPT trial (Amico, 2015; Chemnasiri, 2015; Franks, 2015), a three-country study exploring the feasibility and acceptability of daily; event-based; and time-based PrEP. ADAPT found that those following a non-daily dosing regimen had significantly lower adherence than those following a daily dosing regime in young Black women in Cape Town, South Africa. The same study found that daily dosing provided the best coverage in MSM and transgender women in Harlem, New York. In the Harlem group, participants were most likely to miss the post-sex doses of PrEP. These findings, along with this thesis, contribute to the further knowledge about the pros and cons of different PrEP based regimes.

This research, coupled with my own findings, demonstrates that intermittent PrEP may become far more compelling for men whose risk is occasional or episodic. For such men, taking a short course of PrEP prior to a holiday, or a particular occasion, is likely to be more acceptable and justifiable. However, questions remain about how intermittent PrEP might be used and managed by infrequent risk takers. These questions include: the extent to which side effects, if and when they occur, might (re)appear at each dosing period, and if side effects experienced on a first dosing period might inhibit later intermittent dosing; the optimal days prior to sex that PrEP should be taken; and how long PrEP remains protective following sex. Once again, this indicates how PrEP health promotion needs to be nuanced, specific and tailored to different sex patterns, whilst acknowledging that men's sex patterns do not remain static.

Whilst non-daily PrEP offers further attraction to men who have regular sex patterns, data described in Chapter 4 illustrate how men are not always good at predicting when sex will occur (Parsons et al., 2014). As highlighted in the results section, increased use of GPS-based sexual networking apps make finding and getting sex on-demand, rather than pre-planned, more common. As such, PrEP methods that require pre-planning are less amenable to those who have spontaneous encounters.

In summary, non-daily PrEP is likely to be less useful, and less acceptable, to men who have higher numbers of sexual risky encounters, and for men who have spontaneous, rather than pre-planned sex. As long as efficacy evidence on non-daily PrEP, especially for more regular risk takers, is less compelling than it is for daily PrEP, it will remain less acceptable. Non-daily PrEP offers more attraction to men whose risk is not seen to be sufficient to warrant daily PrEP but who have infrequent episodes of sex that might merit considering event-based use. Regardless of the evidence on efficacy of non-daily PrEP, there will be some men who will hold a preference to daily dosing – as this better fits the way they would prefer to take pills.

8.3.3 Topical PrEP

Again, since the initiation of fieldwork for this thesis, increasing evidence on the use of topical PrEP has emerged (Carballo-Diequez et al., 2014). However, this global research has offered fewer opportunities to address men's acceptability of topical PrEP, compared with other PrEP formats. This research described in this thesis is significant in that it represents the only UK based study that addresses topical PrEP acceptability in MSM. As described in Chapter 5, topical PrEP was by far the least acceptable method of PrEP for men in this study, for a number of reasons.

The fact that a significant number of men said that they tended not to pre-plan their sex, meant that topical PrEP was unappealing. The need for pre-application of topical PrEP (at least based on current efficacy studies of vaginal microbicides) was one of the most significant barriers to rectal microbicide acceptability, although, as with other methods, greater efficacy could influence the extent it is considered acceptable in the future.

Having a formulation of rectal PrEP that could be used instantaneously, such as with a lubricant, would further increase the acceptability of rectal microbicides. However, a significant number of men still found topical PrEP less acceptable because of other factors including concerns about dosing, application and the potential impact on sex.

This study's findings support Kinsler et al's (2011) findings on the acceptability of rectal microbicides in four South American cities. This study used conjoint analysis to predict hypothetical products. As with my research, efficacy and effectiveness of rectal microbicides had the greatest impact on men's acceptability of hypothetical products,

although Kinsler also found that the impact of other product characteristics, such as cost, formulation and side effects, varied by city, even within the same regions.

Given the current evidence and stage of product development of rectal microbicides, the study found that rectal microbicide acceptability is unlikely to improve, despite considerable international advocacy for its further development, until significant research breakthrough of product developments occurs. Developing formulations of rectal microbicide that can either be used alongside preparation for sex (such as rectal douches) or during sex (such as lubricants) will greatly improve such acceptability for some men.

8.3.4 Injectable PrEP

Given the similarities and overlaps between all types of injectable PrEP, monthly and slow-release injectable methods are discussed in this section together. As with rectal microbicides, this is the only UK research that addresses acceptability of injectable PrEP amongst MSM. As was seen in Chapter 5, men who held concerns about forgetting to take daily doses of PrEP viewed injectable PrEP favourably. It was also seen to be more acceptable, in ways similar to daily oral PrEP, by men whose sexual activity was not pre-planned and who could see the benefits of on-going PrEP use.

It is perhaps telling that the one participant who was using PrEP during the time of field work, as well as the other participant who had sought PrEP, found slow-release injectable methods to be more acceptable than most of the other men in the study. This might suggest that there could be a PrEP acceptability continuum: that once men have considered PrEP acceptable enough to take, and have taken or deeply contemplated one method, the opportunities to explore and consider (more convenient) methods might become more acceptable. The acceptability of developing new PrEP methods with current users, in addition to non-users of PrEP, and as such, merits further research and investigation.

Whilst some men viewed injectable PrEP as being “vaccine like” and therefore considered it more effective, others identified concerns that injectable PrEP would become less efficacious towards the end of an injection cycle. That further recent evidence now strongly indicates that injectable PrEP offers more ‘forgiveness’ (Spreen

et al., 2013) towards the end of an injection cycle offers a more compelling case for its acceptability in the future.

8.3.5 Summary

This discussion sub-section has addressed the relative acceptability of different PrEP methods. Whilst efficacy remains central to notions of acceptability, other dimensions hold importance. How men pre-plan their sex is a key determinant of acceptability by method, as is the frequency of sex, and the frequency of SWC in particular. This research highlights not only that different men have different ways of planning and having sex but the patterns of how individual men plan and have sex changes over time. As such, PrEP researchers and policy makers should be considering the benefits of a mixed market of PrEP methods, where different methods will be suited to men's different needs. As importantly, researchers, policy makers and educators should understand that men will move from method to method (and sometimes back again) according to how men plan their sex, the type of sex they have, their relationship status, and any changes or developments to different PrEP methods (including efficacy of method). Just as contraceptive methods have evolved to a mixed market, according to individual need, this research highlights the potential of a mixed market of PrEP availability.

8.4 Developing a PrEP acceptability framework

In Chapter 2 of this thesis I suggested that current notions of how to understand acceptability of PrEP were insufficient. I highlighted existing concepts of how acceptability has traditionally been framed, not least those drawn up in the literature of contraceptive methods that have focused on measures of efficacy and effectiveness, and on physical user-acceptability, such as leakage.

As explored above, by far the biggest issue pertaining to acceptability raised by men in this study is that of efficacy of PrEP method. Although other acceptability issues were important and common, the extent to which a PrEP method works holds the greatest level of protection against HIV infection outweighs other acceptability measures. However, this does not mean that other factors in acceptability should be disregarded – not least when research is suggesting that different PrEP methods are emerging with

very similar efficacy rates (as was seen in the PROUD trial compared with the Ipergay trial – with both formats of PrEP offering 86% efficacy).

This thesis research adds further to the discourse on notions of good citizenship and of carefree (or careless) risk takers (Highleyman, 2013; King, 2014; McNeil, 2014; Tuller, 2013). Whilst being obviously simplistic opposites, how men frame other men's behaviours (or other men who have condom-less sex) verses how they frame their own behaviours is not unique to PrEP. The emergence of PrEP offers further dimensions in the good verses bad gay: it is not uncommon for PrEP users online to voice stigmatising discourse towards non-PrEP users, whilst in the same forum, PrEP users display the stigmatising examples they have received from non-PrEP using men. The recent emergence of (albeit a very small number of) PrEP users who have sero-converted stand to offer a further dimension of stigmatisation: the PrEP user who did not adhere to his PrEP regime, or who otherwise 'failed' on PrEP. Such narratives feed into the discourse and the challenges of what we see as, and how we view PrEP 'users' (Holt, 2014).

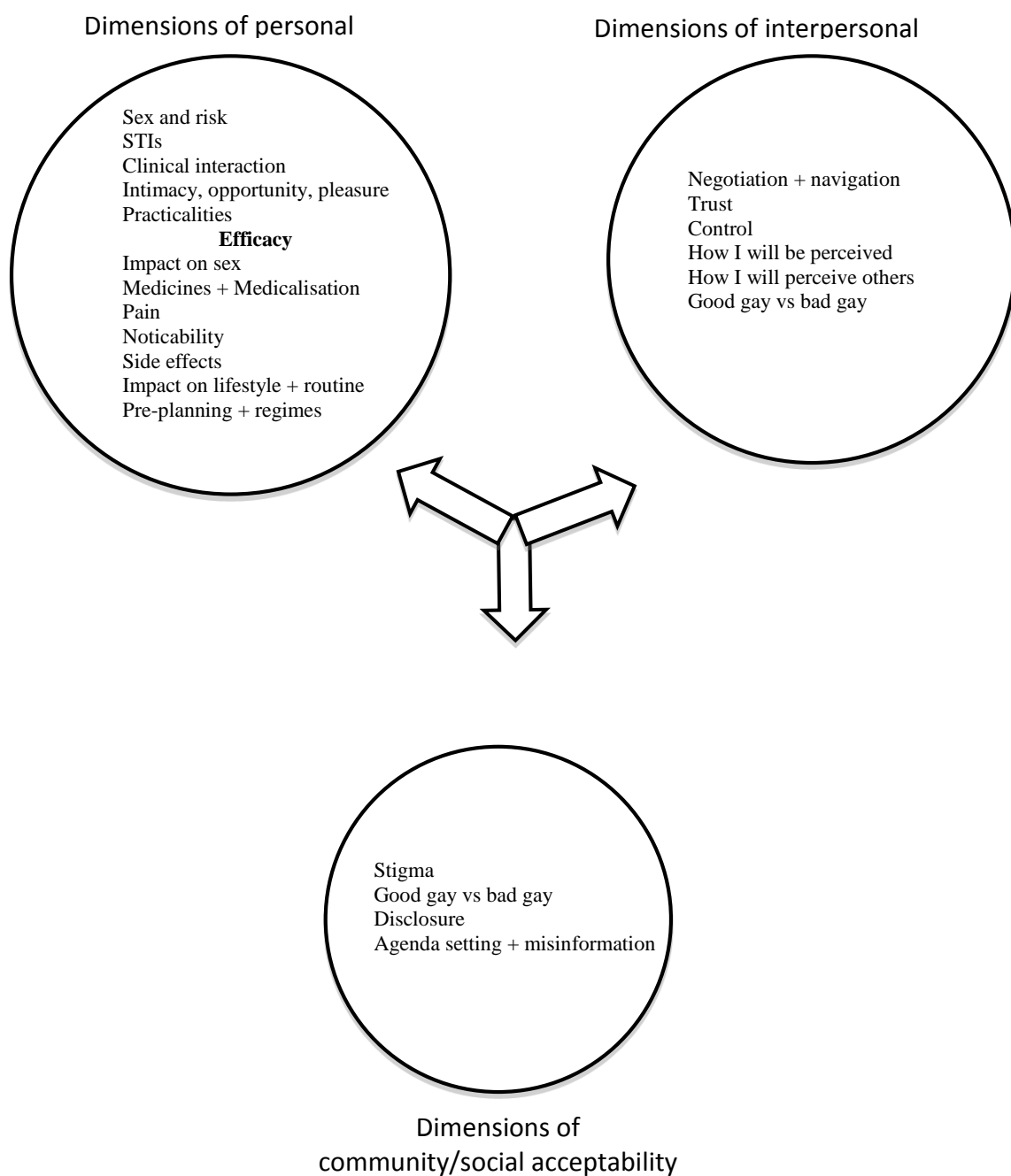


Figure 1: Dimensions of acceptability

As such, it can be determined that dimensions of acceptability are far more complex than presented in much of the existing literature on new prevention technologies. I have outlined the multiple dimensions of personal acceptability in Chapter 5, ranging from those dimensions most commonly raised in existing literature (such as side effects and physical impacts) and those infrequently addressed in the literature (such as the possibilities of PrEP – such as pleasure, intimacy and reductions in stress). These are

presented in Figure 1 with efficacy being presented as the central and most over-riding dimension of personal PrEP acceptability. The complex interaction between inter-personal and community or societal dimensions of acceptability, and their impact on the personal dimensions should not be under-played. They are presented in Figure 1 as multi-directional and over-lapping processes – with community or societal dimensions impacting on inter-personal dimensions (which in themselves will impact on personal acceptability), and community or societal dimensions impacting directly on personal acceptability (which then impacts on inter-personal dimensions). This raises implications of the complexities of understanding concepts of acceptability (and even more so of how a health promoter might seek to influence acceptability, at any level). Those seeking to undertake future research or practice into PrEP acceptability should understand that ‘acceptability’ means far more than whether a technology will work, whether people will be willing to use it, or whether it will cause side effects. Acceptability models need to capture social dimensions, and understand that personal considerations are shaped – and in themselves shape and influence – inter-personal and community or societal dimensions.

[8.5 Contributing to the evidence-base on PrEP and its acceptability](#)

The acceptability of using PrEP to prevent HIV infection has been an under-researched area and since fieldwork for this research has been undertaken further research on PrEP acceptability has been more broadly undertaken (Aghaizu et al., 2012; Frankis et al., 2014; Thng et al., 2012; Young et al., 2013). In general, these studies have focused on the views of groups with highest incidence and prevalence, and people with HIV and their partners, but not necessarily those who have recently been exposed to HIV (Young et al., 2013). However, this research study is the first to focus on MSM in London who do not have HIV but are within a population, both geographically and epidemiologically, with a high prevalence of HIV.

Although international research has been conducted into the acceptability of topical PrEP, this has largely focused on vaginal microbicide use amongst women. Almost the entire published research on topical PrEP and MSM has focused on low or middle-income countries or, when research has been undertaken in a high-income setting, North America has predominated. This is the first UK research to address the acceptability of

topical PrEP in MSM, and the first to explore potential barriers to using a rectal microbicide in the UK.

And, although the England PROUD study has now started exploration of PrEP acceptability and feasibility in MSM who are using PrEP (albeit in a clinical trial), this doctoral research is the only available research from England to explore *potential* PrEP acceptability in men who are not using it (with the exception of one participant) during a period when public and social discourse on PrEP was relatively minimal. As such, this study enhances the research agenda on the potential acceptability and use of PrEP in men who were relatively PrEP-naïve, and assists in evidencing future PrEP education and service needs. In addition, this research is unique in that it is the only UK research that explores comparative acceptability of PrEP by different methods including those methods that, at the time, were broadly still in concept or pipeline development phase.

Finally, whilst other social research has started to evidence how community and social actors might influence potential PrEP uses, including the impact of stigma, this is the only existing UK research that explores how men might respond to *another* man's use of PrEP, thereby exposing the contradictions in men's own narratives between concepts of self, and concepts of other.

With these novel findings in mind, the final chapter of this thesis considers recommendations relating to PrEP provision, future research and lobbying or advocacy.

Chapter 9: Conclusion

In this concluding chapter, I return to the final objective of this thesis and establish recommendations for potential PrEP providers, for PrEP health promotion interventions, and those responsible for the commissioning and funding of these. These recommendations are based on this study's research findings, supported by other current and emerging evidence on PrEP.

In the course of researching and writing this thesis, our collective knowledge of, and access to PrEP has increased. In the first wave of interviews for this study, the England PROUD study was not recruiting, yet by the final set of interviews, men had the opportunity to enroll into and access PrEP, albeit on a trial basis, in the UK's first clinical PrEP trial. In addition, a number of gay community media (Azad, 2015a) and mainstream media publications (Cairns, 2014a; Holpuch, 2014; Tuller, 2013) featured news stories about PrEP, including individual men's accounts of using this new HIV prevention technology. By the point of completion of this thesis, developments in Europe, and England in particular, further fast-tracked a collective dialogue about PrEP availability. Those dialogues have included the free availability of PrEP on the NHS, including how PrEP might be resourced (by NHS England, through local authority public health budgets, through Clinical Commissioning Groups, or a combination of all); *who* PrEP might or should be available to and the decisions about how availability might be decided; and the moral and ethical dilemmas of if and how a cohort of men on existing PrEP clinical trials, many of whom have integrated PrEP centrally into their HIV risk reduction practices, should have PrEP available to them once clinical trials have ceased. The early closure of PROUD's deferred arm and the cessation of Ipergay's placebo arm that followed have further added to an emerging urgency to resolve PrEP prescribing policy and availability (Nutland, 2014).

With this in mind, it is likely that knowledge about and use of PrEP is growing. Given the coverage described above, it is reasonable to assume that MSM in London – particularly those connected with particular social and sexual networks – know more about PrEP than they did at the start of data collection for this research. Indeed, there

have been suggestions that some men are starting to use PrEP outside of clinical trials, in some cases through online purchase or by using friend's supplies, and not always with the support of medical interventions to monitor and support their use (Azad, 2015b). As such, the recommendations that follow focus not only on assumptions of future population based use of PrEP, but also acknowledge that a small but growing number of men would benefit from PrEP interventions now, rather than waiting to see if and when PrEP is available on the NHS.

It should be acknowledged that, although these recommendations are based on the study's research findings, they are additionally shaped by my former experience and career as an HIV health promoter. As is appropriate within the scope of an applied research doctorate, these recommendations are intended to shape and influence health promotion policy and practice, based upon and embedded within my professional experience.

9.1 Recommendations for future research

Recommendation 1: Research should be conducted into the efficacy, efficiency and acceptability of topical, injectable and other (non-oral) emerging PrEP application methods.

As this research found, no single method of PrEP was ideally suited to every man. Whilst daily oral PrEP was the most acceptable method – in part because it was the only available and therefore the most tangible technology – other PrEP technologies need to be developed that offer at risk populations a range of technologies that meet the complex and differing needs of MSM. Such technologies need to account for the different use and differences in physiology in key HIV at-risk target groups and to take into account people's 'seasons' of risks, and how PrEP users might jump between different PrEP methods, according to their risk taking at any point in time.

Recommendation 2: Further research should examine the longer-term impact of daily or regular Truvada use and, in tandem, PrEP methods using alternative drugs, which might be less toxic, should be developed.

This research highlights men's concerns about the side effects – especially the longer-term side effects - of PrEP, and the impact of side effects on PrEP acceptability. It is important that longer-term cohort studies are undertaken that examine the toxicity effects of PrEP over the longer term so that men are able to make informed choices as to its use.

Recommendation 3: Further research should be undertaken to pilot and up-scale interventions that increase knowledge and awareness of PrEP, and build skills and abilities in accessing and using PrEP.

This research should be undertaken along PrEP health promoters and service providers (see Recommendation 7 below).

9.2 Recommendations for development of policy and lobbying

Recommendation 4: Community-based organisations and national partnerships should make clear and unambiguous statements on PrEP and build further consensus and collaboration on PrEP policy and practice.

It is telling that none of the men in this study had heard about PrEP from community-based organisations. In some instances a perceived silence about PrEP from such organisations made men suspicious about PrEP. Despite recent PrEP community statements (PrEP Access, 2014), community-based leadership on PrEP has been cautious, and on some occasions ambiguous (Mundasad, 2014). In doing so, community-based organisations can build social capital and empower key at-risk communities to take action on PrEP and to develop better peer-led and community-led education interventions.

Recommendation 5: HIV organisations should position PrEP *alongside* other forms of HIV risk reduction - all of which have benefits and costs - and should recognise that PrEP use and availability is a valid method that may be used in conjunction with condoms and, on occasion, instead of condoms.

Stigma and taboo around PrEP use and/or sex without condoms has been identified as a major barrier to PrEP use and discussion about its use. As such, HIV organisations and policy makers should continue to work to de-stigmatise HIV and sex, including through developing policies and programmes that promote the best sex with the least harm.

9.3 Recommendations for commissioning of PrEP services

Recommendation 6: PrEP services should be embedded within a broad range of educational, psychological and behavioural services, that attempt to address a man's wider (HIV related) (sexual) health needs, rather than a 'stand-alone' service.

For PrEP clinical providers, opportunities exist to offer 'wrap-around' services, or alternatives to PrEP, that may better meet those men's needs other than PrEP provision. As such, as PrEP provision develops, PrEP should be offered and made available within a holistic health service that offers services around sexual health, drug and alcohol support, and mental health support. For some men, their health needs may be better met by interventions other than PrEP provision, even if a desire for PrEP was the reason for presenting at a service.

Recommendation 7: Health promoters should, in conjunction with researchers, plan, pilot and up-scale interventions that increase knowledge and awareness of PrEP, and build skills and abilities in accessing and using PrEP.

These should over-serve those with greatest HIV prevention and PrEP need (see Recommendation 11 below). Education and awareness interventions around PrEP should recognise how PrEP will be used alongside other risk reduction strategies including condom use, decisions about whether to top or bottom, and discussions around HIV testing or viral load detectability in HIV positive partners. PrEP does not replace or make these strategies irrelevant or unnecessary. Those providing PrEP health promotion should review educational frameworks, strategies and interventions so that potential PrEP use is accounted for and incorporated, including sex negotiation strategies and options.

Recommendation 8: A well-planned and well-resourced knowledge transfer and training programme for policy makers and health professionals and community based health promoters – especially front line staff – should be developed.

Research from the USA and a range of developing countries has demonstrated that the capacity and ability of policymakers and health professionals to respond to PrEP can be a barrier to PrEP access (Arnold, 2012; Wheelock et al., 2012). This is likely to be the case for policy makers, health practitioners and health promoters in the UK too, especially given the fast changing evidence about PrEP. Such a programme should frame PrEP alongside other HIV prevention and sexual health tools and interventions, and enables those seeking information about PrEP, or those seeking access to PrEP to have the best control over their own PrEP based health needs.

9.4 Recommendations for PrEP service delivery

Recommendation 9: Consideration should be given to the merits of prescribing guidelines based only on a sexual risk-taking algorithm.

Whilst acknowledging the importance of cost-effectiveness considerations in prescribing PrEP primarily to men at highest risk of HIV acquisition, consideration should be given to the broader (sexual) health benefits of PrEP prescription to those taking fewer HIV risks but who may additionally benefit from PrEP. These may include the negative partners of men with HIV who have undetectable viral loads; men whose occasional SWC causes anxiety, stress or depression; and those men who experience sexual dysfunction during condom use. Whilst some of these needs might be met by having ‘wrap-around’ services for those presenting for PrEP (see below), PrEP prescribing guidelines need to allow for individual clinician flexibility in making PrEP prescribing decisions on a case-by-case basis.

Recommendation 10: Providers of PrEP health promotion services (and the commissioners of them) should research, plan, pilot and upscale interventions, drawing on a broad range of methods that support, enable and facilitate access to PrEP and its use.

Both providers of clinical PrEP services and those providing a broad range of PrEP health promotion services have the potential to enhance PrEP effectiveness – such as supporting adherence or assisting in managing side effects. Evidence from PrEP implementation demonstrates the importance – especially for more marginalised or vulnerable populations – of PrEP support. Such interventions might include developing skills on PrEP disclosure and sexual negotiation; adherence support; and skills building for those starting and stopping PrEP.

Recommendation 11: Further service development should be undertaken, driven by research and evidence based practice, which enhances service access for those most in need of HIV prevention and PrEP related services.

From the perspective of NHS sexual health service provision, there stands a danger that PrEP delivery may lead to a two-tier system. That is: that those prescribed PrEP may get (or expect) a ‘gold-standard’ sexual health clinic service (such as regular appointments, fast-tracked services, dedicated staff members) and those (who may have the same or greater need) who may not benefit from the additional benefits of being on PrEP. This might include, but not be restricted to, provision of targeted and tailored services, accessible only to those most at-risk groups (e.g. MSM only services).

Recommendation 12: Those planning PrEP clinical services and those providing PrEP educational interventions should account for how they intend to reduce inequalities and how they intend to over-serve those in greatest HIV need.

Given the research evidence that exists around health inequalities and access to health technologies, the introduction of a new HIV prevention technology provides opportunities to plan and build strategies around reducing those health inequalities, not least regarding access to and awareness of it. Evidence from PrEP implementation pilots and other research (Holpuch, 2014; Hosek, 2013; Rodriguez, 2014) continue to highlight how key communities – such as young Black MSM – are underserved or neglected by PrEP interventions. Over two decades of HIV prevention research in the UK has highlighted how Black gay men, migrant men, younger men, and men with lower educational qualifications should be over-served by HIV prevention, yet most

existing prevention programmes have failed, or have been unable to re-configure their services to over-serve such men. The introduction of PrEP provides an opportunity for prevention programmes, and how they fail to over-serve such men, to be reviewed and revised. This might include providing enhanced PrEP support, including adherence support, or focused outreach interventions, to key groups.

Recommendation 13: HIV prevention interventions should continue to challenge naïve risk takers' beliefs that they are not taking HIV related risks.

As discussed in the preceding chapter, those men who are at risk of HIV acquisition, but who fail to recognise their risk-taking, are those who will least benefit from PrEP availability. Such strategies should include: raising awareness of the prevalence of HIV in MSM communities; increasing awareness that a significant proportion of men with HIV do not know that they have it; undermining men's beliefs that all men with HIV know they have it, always disclose their HIV status, always use condoms during anal intercourse, or would not have SWC without discussing their own, or their partner's, HIV status. Such approaches should be undertaken in a way that challenges naïve risk takers' world beliefs, without undermining the human rights or dignity of people with HIV, nor stigmatising those living with HIV.

Recommendation 14: Health promoters should embed PrEP health promotion interventions within established ethical frameworks, including those described in Making it Count (CHAPS Partnership, 2011)

For those developing PrEP educational interventions, it is important that those should be done within the context of how men might and do use PrEP. These should recognise the varying and complex ways that men negotiate sex and risk and how, for many men, PrEP might make this more complex. Further, such interventions should recognise how PrEP is being used or will be used, rather than how 'we' (health promoters, commissioners, public health professionals) might *desire* PrEP to be used. PrEP offers an opportunity for those delivering HIV health promotion to (re)engage and interact with key target groups in the reality of how sex and risk happens. Being seen to enforce a set of PrEP 'rules' or judgments relating to its use will be a missed opportunity for HIV health organisations to build engagement and dialogue with those most in need of

PrEP interventions. As such, PrEP health promotion cannot (and should not) be diluted in to a set of “messages”. Sex and risk are already complex and the introduction of PrEP makes it more so. Thoughtful, well-developed and evidence informed interventions that assist men in navigating and negotiating sex in an ever-complex era need to be developed. They need to take into account men’s current risk-reduction strategies, and that many men will use PrEP in *conjunction* with their existing strategies. They also need to accept (and not demonise) that some men, on some occasions, will use PrEP *instead* of their prevalent risk reduction strategies.

References

- ABDOOL KARIM, Q. & ABDOOL KARIM, S. (2010) Effectiveness and safety of tenofovir gel, an antiretroviral mircobicide, for the prevention of HIV infection in women. *Science*, 329, 1168-74.
- AGENCY NATIONALE DE RECHERCHES SUR LE SIDA ET LES HEPATITES VIRALES. (2012) *ANRS launches first PrEP trial for gay men in Europe* [Online]. Available: <http://www.anrs.fr/VIH-SIDA/Sante-publique-Sciences-sociales/Actualites/Communique-de-presse-L-essai-ANRS-PrEP> [Accessed 18/09/2015].
- AGHAIZU, A., BROWN, E., NARDONE, A. & ET AL. (2013) *HIV in the United Kingdom 2013 Report: data to end 2012*. London, UK: Public Health England.
- AGHAIZU, A. (2012) Who would use PrEP? Predictors of use among MSM in London. *Annual Conference of the British HIV Association*. Birmingham.
- ALLEN, K. (2003) *HIV partners 'should get drugs'*. [Online] Available: <http://news.bbc.co.uk/1/hi/health/3258163> [Accessed 12/12/15]
- AMICO, K. (2015) PrEP experiences among South African women in the HPTN067 (ADAPT) study. *Eighth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention*. Vancouver, Canada.
- ANDREWS, C (2013) Long-acting parenteral formulation of GSK1265744 protects macaques against repeated intrarectal challenges with SHIV. *20th CROI Conference*. Atlanta, USA.
- ARNOLD, E., HAZLETON, P., LANE, T. & ET AL. (2012) A qualitative study of provider thoughtst on implemnting pre-exposure prophylaxis (PrEP) in clinical settings to prevent HIV infection. *PLoS ONE*, 7
- AYALA, G. & ELDER, J. (2011) Qualitative methods to ensure acceptability of behavioral and social interventions to the target population. *J Public Health Dent*, 71, 69-79.
- AZAD, Y. (2015a) Buying PrEP Online: The risks. *QX Magazine*. London, UK.
- AZAD, Y. (2015b) PrEP works! Results of the PROUD study announced. *Dirty Boyz*. London.
- BAZELEY, P. (2007) *Qualitative Data Analysis with NVivo*, London, Sage Publishers.
- BECK, U. (1992) *Risk Society: Towards a New Modernity*, London., Sage.
- BOERNER, H. (2014) The world's most effective HIV prevention drug hasn't lived up to its potential. *The Washington Post*, November 2 2014.
- BOURNE, A., DODDS, C., KEOGH, P. & ET AL. (2015) *Non-condom related strategies to reduce the risk of HIV transmission: Perspectives and experiences of gay men with diagnosed HIV* [Online].
- BOURNE, A., DODDS, C., KEOGH, P., WEATHERBURN, P. & HAMMOND, G. (2009) Relative Safety II - risk and unprotected anal intercourse among gay men with diagnosed HIV. London: Sigma Research.
- BOURNE, A., HAMMOND, G. & HICKSON, F. (2013) What constitutes the best sex life for gay and bisexual men? Implications for HIV prevention. *BMC Public Health*, 13, 1083.
- BOURNE, A., HICKSON, F. & KEOGH, P. (2012) Problems with sex among gay and bisexual men with diagnosed HIV in the United Kingdom. *BMC Public Health*, 12, 916.
- BOYATZIS, R. (1998) *Transforming Qualitative Information*, Cleveland, USA, Sage.

- BRAUN, V. & CLARKE, V. (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3, 77-101.
- BRONFENBRENNER, U. (1979) *The Ecology of Human Development: Experiments by Nature and Design*, Cambridge, Massachusetts, Harvard Uni Press.
- BROOKS, A., KAPLAN, RC., LIEBER, R. & ET AL (2011) Motivators, concerns, and barriers to adoption of pre-exposure prophylaxis for HIV prevention among gay and bisexual men in HIV sero-discordant male relationships. *AIDS Care*, 23, 1136-1145.
- BUCHBINDER, S. & LIU, A. (2011) Pre-exposure prophylaxis and the promise of combination prevention approaches. *AIDS Behaviour*.
- BUSTON, K., PARRY-JONES, W., LIVINGSTON, M. & ET AL. (1998) Qualitative research. *British Journal of Psychiatry*, 172, 197-199.
- CAIRNS, G. (2014a) D-day for the pill for HIV. *Huffington Post*.
- CAIRNS, G. (2014b) European CDC cautious about PrEP: more research needed before European approval, EU Centre for Disease Control says. Available: <http://www.aidsmap.com/print/European-CDC-cautious-about-PrEP/page/2891977/> [Accessed 18/09/2015].
- CAMBIANO, V. (2015) Is pre-exposure prophylaxis for HIV prevention cost-effective in men who have sex with men who engage in condomless sex in the UK? *British Association of Sexual Health and HIV*. Glasgow, UK.
- CARBALLO-DIEGUEZ, A., GIGUERE, R., DOLEZAL, C. & ET AL. (2014) Rectal-specific microbicide applicator: evaluation and comparison with a vaginal applicator used rectally. *AIDS Behaviour*, 18, 1734-45.
- CASTEL, R. (1991) From dangerous to risk. In: BURCHELL, G., GORDON, C. & MILLER, P. (eds.) *The Foucault Effect: Studies in Governmentality*. London.: Harvester/Wheatsheaf.
- CHAPS PARTNERSHIP. (2011) *Making it Count 4: a collaborative planning framework to minimise the incidence of HIV during sex between men*. 4th ed. London.
- CHARMAZ, C. (2006) *Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis.*, London. Sage Publishers.
- CHEMNASIRI, T. (2015) Patterns of sex and PrEP in Bangkok MSM (HPTN 067/ADAQPT Study). *Eighth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention*. Vancouver, Canada.
- CHEN, B., PANTHER, L., HOESLEY, C. & ET AL. (2014) Safety and Pharmacokinetics/Pharmacodynamics of Dapivirine and Maraviroc Vaginal Rings. *21st Conference on Retroviruses and Opportunistic Infections*. Boston, USA.
- COHEN, J. (2014) A bid to thwart HIV with shot of long-lasting drug. *Science*.
- COHEN, M. & BADEN, L. (2012) Pre-exposure Prophylaxis for HIV – where do we go from here? *New England Journal of Medicine*, 367, 5.
- COHEN, M., CHEN, Y., MCCAULEY, M. & ET AL. (2011) Antiretroviral treatment to prevent the sexual transmission of HIV-1: results from the HPTN 052 multinational randomized controlled trial. *6th IAS Conference on HIV Pathogenesis, Treatment and Prevention*. Rome.
- COOPER, L., HILL, M. & POWE, N. (2002) Designing and evaluating interventions to eliminate racial and ethnic disparities in health care. *Journal of General Internal Medicine*, 17, 477-486.

- CORNWALL, L. (1984) *Hard earned lives: accounts of health and illness from East London*. London, Tavistock.
- DAS DOUGLAS, M. & CHU, P. (2010) Decreases in community viral load are associated with a reduction in new HIV diagnoses in San Francisco. *17th Conference on Retroviruses and Opportunistic Infections*. San Francisco, USA.
- DESAI, K. (2008) Modeling the impact of HIV chemoprophylaxis strategies among men who have sex with men in the United States: HIV infections prevented and cost-effectiveness. *AIDS*, 22, 1829-1839.
- DOUGLAS, M. (1969) *Purity and Danger: An Analysis of the Concepts of Pollution and Taboo*. London., Routledge and Kegan Paul.
- ECDC. (2015) *Pre-exposure prophylaxis to prevent HIV among MSM in Europe*. Press release.
- EISINGERICH, A., WHEELOCK, A., GOMEZ, G. & ET AL. (2012) Attitudes and Acceptance of Oral and Parenteral HIV Preexposure Prophylaxis among Potential User Groups: A Multinational Study. *PLoS ONE*, 7.
- ELIAS, C. & COGGINS, C. (2001) Acceptability research on female-controlled barrier methods to prevent heterosexual transmission of HIV: where have we been? Where are we going? *Journal of Women's Health and Gender-Based Medicine*, Mar 2001, 163-73.
- ELLIOT, R; FISCHER, CT. & RENNIE, DL. (1999) Evolving guidelines for publication of qualitative research studies in psychology and related fields. *British Journal of Psychology*, 38, 215-229.
- EMIS. (2013) *The European Men Who Have Sex With Men Internet Survey: Findings from 38 Countries*. Stockholm: European Centre for Disease Prevention and Control.
- EVANS, D. (2012) Getting practical about PrEP. *Poz Magazine*.
- EVANS, D. & VAN GORDER, D. (2013) PrEP should be a fast idea, not a slow one. *Huffington Post*.
- EWALD, F. (1991) Insurance and Risks. In: BURCHELL, G., GORDON, C. & MILLER, P. (eds.) *The Foucault Effect: Studies in Governmentality*. London.: Harvester/Wheatsheaf.
- FDA. (2012) FDA approves first drug for reducing the risk of sexually acquired HIV infection.
- FISH, J. & KARBAN, K. (2015) *Lesbian, Gay, Bisexual and Trans Health Inequalities* Bristol, UK, Policy Press.
- FISHER, M., BENN, P. & EVANS, B. (2006) UK guidelines for the use of post-exposure prophylaxis for HIV following sexual exposure. *International Journal of STD & AIDS*, 17, 81-92.
- FRANKIS, J. & FLOWERS, P. (2005) Men who have sex with men (MSM) in public sex environments (PSEs): a systematic review of quantitative literature. *AIDS Care*, 17, 273-288.
- FRANKIS, J. & FLOWERS, P. (2009) Public sexual cultures: a systematic review of qualitative research investigating men's sexual behaviours with men in public spaces. *Journal of Homosexuality*, 56, 861-893.
- FRANKIS, J., YOUNG, I., FLOWERS, P., & McDAID, L. (2014) Understanding the acceptability of pre-exposure prophylaxis (PrEP) for HIV prevention amongst gay and bisexual men in Scotland: a mixed-methods study. *Third Joint Conference of BHIVA and BASHH*. Liverpool, UK.

- FRANKS, J. (2015) Patterns of sex and PrEP in Harlem MSM: A qualitative study (HPTN 067). *Eighth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention*. Vancouver, Canada.
- GAFOS, M. (2013) *Microbicides, Sexuality and Sexual Health in KwaZulu-Natal, South Africa*. City University, London.
- GALEA, J., KINSLER, J., SALAZAR, X. & ET AL (2011) Acceptability of pre-exposure prophylaxis as an HIV prevention strategy: barriers and facilitators to pre-exposure uptake among at-risk Peruvian populations. *International Journal of STD & AIDS*, 22, 256-262.
- GARNER, A. (2012) There's no shame in PrEP. *Huffington Post*.
- GIBBS, J. (2011) Treatment as prevention. *A&U Magazine*. 14 November 2011.
- GLASER, B. G. (1992) *Emergence vs. Forcing: Basics of Grounded Theory Analysis*, Mill Valley, CA., The Sociology Press.
- GLAZEK, C. (2013) Why is no one on the first treatment to prevent HIV? *New Yorker*, 30 September 2013.
- GOLUB, S. (2010) Preexposure prophylaxis and predicted condom use among high-risk men who have sex with men. *J Acquir Immune Defic Syndr* [Online].
- GOLUB, S. & GAMAREL, K. (2014) 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, 177-186.
- GOMEZ, G., BORQUEZ, A., CACERES, C. & ET AL. (2012) The potential impact of pre-exposure prophylaxis for HIV prevention among men who have sex with men and transwomen in Lima, Peru: a mathematical modelling study. *PLoS Medicine*, 9.
- GRANT, R. (2006) Cost-effectiveness analysis of HIV chemoprophylaxis. *Sixteenth International Aids Conference*. Toronto.
- GRANT, R. (2014) Results of the iPrEx open-label extension (iPrEx OLE) in men and transgender women who have sex with men: PrEP uptake, sexual practices, and HIV incidence. *20th International Aids Conference*. Melbourne, Australia.
- GRANT, R., LAMA, J., ANDERSON, P. & ET AL (2010) Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex With Men. *The New England Journal of Medicine*, 363, 2587-2599.
- GREEN, J. & THOROGOOD, N. (2004) *Qualitative Methods for Health Research*, London, Sage Publishers.
- GRINDLEY, L. (2014) Put away the pitchforks and let's talk about PrEP. *Advocate*.
- GROHSKOPF, L. 2010. Preliminary analysis of biomedical data from the phase II clinical safety trial of tenofovir disoproxil fumarate (TDF) for HIV-1 pre-exposure prophylaxis (PrEP) among U.S. men who have sex with men (MSM). *Eighteenth International AIDS Conference*. Vienna.
- GROV, C., RENDINA, J., RAYMOND, L. & ET AL (2015) HIV sero-sorting, status disclosure and strategic positioning among highly sexually active gay and bisexual men. *AIDS Patient Care and STDs*, 29, 559-568.
- GUEST, G., SHATTUCK, D. & JOHNSON, L. (2010) Acceptability of PrEP for HIV Prevention Among Women at High Risk for HIV. *Journal of Women's Health* 19, 791-798.
- HEALTH PROTECTION AGENCY. (2011) HIV in the United Kingdom: 2011 Report. London.

- HEITZ, D. (2015) Injectable PrEP? It may be available sooner than you think. *HIV Equal*, 14 June 2015.
- HENDERSON, L., KEOGH, P., WEATHERBURN, P. & ET AL. (2001) *Managing uncertainty: risk and unprotected anal intercourse among gay men who do not know their HIV status*. London, UK: Sigma Research.
- HERBST, J., BEEKER, C. & MATHEW, A. (2007) The effectiveness of individual, group, and community-level HIV behavioral risk-reduction interventions for adult men who have sex with men: a systematic review. *American Journal of Preventative Medicine*, S38-67.
- HERBST, J., SHERBA, R. & CREPAZ, N. (2005) The HIV/AIDS Prevention Synthesis Team: a meta-analysis review of HIV behavioral interventions for reducing sexual risk taking behavior of men who have sex with men. *Journal of Acquired Immune Deficiency Syndrome*, 228-41.
- HEYWOOD, T. (2014) PrEP dissent rooted in gay culture shifts, lower Aids mortality. *The Body*, 15 November 2014.
- HIGHLEYMAN, L. (2011) CDC offers PrEP guidance. *Bay Area Reporter*, 3 February 2011.
- HIGHLEYMAN, L. (2014) AHF PrEP Ad Controversy: what do the numbers mean? *BETA*.
- HOLPUCH, A. (2014) Truvada has been called the 'miracle' HIV pill - so why is uptake so slow? *The Guardian*, 18 September 2014.
- HOLT, M. (2014) Configuring the users if new HIV-prevention technologies: the case of HIV pre-exposure prophylaxis. *Culture, Health & Sexuality*.
- HOSEK, S. (2013) Project PrEPare (ATN082): the acceptability and feasibility of an HIV pre-exposure prophylaxis (PrEP) trial with young men who have sex with men (YMSM). *J Acquir Immune Defic Syndr*.
- IPREX OLE. (2012) *What are the aims of iPrEx OLE?* [Online]. Available: <http://iprexole.com/1pages/aboutus/aboutus-lookingat.php> [Accessed 13/01/2012 2012].
- JACKSON, A. (2012a) Rilpivirine-LA formulation: pharmacokinetics in plasma, genital tract in HIV- females and rectum in males. *19th Conference on Retroviruses and Opportunistic Infections*. Seattle, USA.
- JACKSON, A. (2012b) Rilpivirine-LA formulation: pharmacokinetics in plasma, genital tract in HIV- females and rectum in males. *19th Conference on Retroviruses and Opportunistic Infections*. Seattle.
- JOFFE, H. (1999) *Risk and 'The Other'*, Cambridge, Cambridge University Press.
- JOHNS HOPKINS MEDICINE. (2014) The National Institutes of Health awards \$21 million to research rectal douches.
- JOHNSON, W., HEDGES, L. & RAMIREZ, G. (2002) HIV prevention research for men who have sex with men: a systematic review and meta-analysis. *Journal of Acquired Immune Deficiency Syndrome*, S118-129.
- JOHNSON, W., HOLTGRAVE, D. & MCCLELLAN, W. (2005) HIV intervention research for men who have sex with men: a 7-year update. *AIDS Education Prevention*, 568-89.
- KAMALI, A., BYOMIRE, H. & MUWONGE, C. (2010) A randomised placebo-controlled safety and acceptability trial of PRO 2000 vaginal microbicide gel in sexually active women in Uganda. *Sexually Transmitted Infections*, 86, 222-226.

- KEOGH, P. (2007) Gay men's perceived proximity to HIV: a qualitative analysis. *Eighth AIDS Impact Conference*. Marseille.
- KEOGH, P. (2008) Morality, responsibility and risk: Negative gay men's perceived proximity to HIV. *AIDS Care*, 20.
- KEOGH, P. & WEATHERBURN, P. (2000) Boys from the backroom: anonymous sex and HIV risk in London's commercial gay sex venues. *Venereology*, 13, 150-155.
- KING, M. (2014) *The sound and fury of the PrEP debate (and the facts to win it)* [Online]. Available: <http://marksking.com/my-fabulous-disease/the-sound-and-fury-of-the-prep-debate-and-the-facts-to-win-it/> [Accessed 09 February 2014]
- KINSLER, R., CUNNINGHAM, W., NURENA, C. & ET AL. (2011) Using conjoint analysis to measure the acceptability of rectal microbicides among men who have sex with men in four South American cities. *AIDS Behaviour*, 16, 1436-1447.
- KIRBY, D. (2007) Emerging Answers 2007 - Research Findings on Programs to Reduce Teen Pregnancy and Sexually Transmitted Infections. Washington, DC.
- KIRBY, T. & THORNBUR-DUNWELL, M. (2014) Uptake of PrEP for HIV slow among MSM. *The Lancet*, 383, 399-400.
- LAPADAT, J. & LINDSAY, A. (1999) Transcription in research and practice: From standardization of technique to interpretive positionings. *Qualitative Inquiry*, 5, 64-86.
- LEIBOWITZ, A., PARKER, K. & ROTHERAM-BORUS, M. (2011) A US Policy Perspective on Oral Preexposure Prophylaxis for HIV. *Am J of Public Health*, 101, 982-985.
- LIMA, V., JOHNSON, K., HOGG, R. & ET AL. (2008) Expanded access to highly active antiretroviral therapy: a potentially powerful strategy to curb the growth of the HIV epidemic. *JID*, 198, 59-67.
- LIU, A., COHEN, S., FOLLANSBEE, S. & ET AL. (2014) Early experiences implementing pre-exposure prophylaxis (PrEP) for HIV prevention in San Francisco. *PLoS Medicine*, 11.
- LIVOTI, C. (2012) Gilead not immune to concern over Truvada's wider HIV use. *Financial Times*, 24 January 2012.
- MCCORMACK, S., FIDLER, S. & FISHER, M. (2012) The British HIV Association/British Association for Sexual Health and HIV position statement on pre-exposure prophylaxis in the UK. *International Journal of STD & AIDS*, 23, 1-4.
- MCCORMACK, S., FIDLER, S., FISHER, M. & ET AL. (2015) Updated BHIVA-BASHH statement on PrEP in the UK - consultation paper.
- MCCORMACK, S. (2015) Pragmatic open-label randomised trial of pre-exposure prophylaxis: The PROUD Study. *2015 Conference on Retroviruses and Opportunistic Infections*. Seattle, USA.
- MCGOWAN, I., GOMEZ, K., BRUDER, K. & ET AL. (2011) Phase 1 randomized trial of the vaginal safety and acceptability of SPL7013 gel (VivaGel) in sexually active young women (MTN-004). *AIDS*, 25, 1057-1064.
- MCNEIL, D. (2014) Advocating pill, US signals shift to prevent AIDS. *The New York Times*, 14 May 2014.
- MELLORS, J. (2010) Antiretrovirals for treatment and prevention - two trains on a collision course? *Microbicides 2010 Conference*. Pittsburgh.

- MICROBICIDE TRIAL NETWORK. (2015) Rectal microbicides - fact sheet.
- MIMIAGA, M., CASE, P., JOHNSON, C. ET AL. (2009) Pre-exposure antiretroviral prophylaxis attitudes in high-risk Boston-area men who report having sex with men: limited knowledge and experience but potential for increased utilization after education. *Journal of Acquired Immune Deficiency Syndrome*, 50, 77-83.
- MOLINA, J. (2015) On demand PrEP with oral TDF-FTC in MSM: Results of the ANRS Ipergay Trial. *2015 Conference on Retroviruses and Opportunistic Infections*. Seattle, USA.
- MUNDASAD, S. (2014) Healthy gay men urged to take HIV drugs-WHO. *BBC News*, 11 July 2014.
- NAKAGAWA, F. (2011) Projected life expectancy of people with HIV according to timing of diagnosis. *AIDS Online edition*
- NEWMAN, E. (2015a) Adapting PrEP to match sex patterns. *BETA*. San Francisco Aids Foundation.
- NEWMAN, E. (2015b) Injectable PrEP: the next order of the day. *BETA*. San Francisco Aids Foundation.
- NHS ENGLAND. (2015) Specialised Services Circular: Pre-Exposure Prophylaxis (PrEP) to prevent HIV: clarification of commissioning position. London, UK: NHS England.
- NUTLAND, W. (2014) Why HIV prevention meds should be available on the NHS now. *Newstatesman*.
- ONG, K.-J. (2015) Will HIV PrEP given to high-risk MSM in England be cost-effective? Preliminary results of a static decision analytical model. *Public Health England Conference*. Coventry, UK.
- PACHANKIS, J., HATZENBUEHLER, M., HICKSON, F. & ET AL. (2015) Hidden from health: structural stigma, sexual orientation concealment, and HIV across 38 countries in the European MSM Internet Survey. *AIDS*, 29, 1239-1246.
- PARSONS, J., RENDINA, H., GROV, C. ET AL. (2014) Accuracy of highly sexually active gay and bisexual men's predictions of their daily likelihood of anal sex and its relevance for intermittent event-driven HIV pre-exposure prophylaxis. *J Acquir Immune Defic Syndr*, Early online publication.
- PAXTON, L. A., HOPE, T. & JAFFE, H. W. (2007) Pre-exposure prophylaxis for HIV infection: what if it works? *The Lancet*, 370, 89-93.
- PEBODY, R. (2015) PrEP: HIV prevention briefing paper. NAM. London, UK.
- PETERSON, L. (2006) Findings from a double-blind, randomized, placebo-controlled trial of tenofovir disoproxil fumarate (TDF) for prevention of HIV infection in women. *Sixteenth International AIDS Conference*. Toronto, Canada.
- PINK NEWS. (2011) *Gay HIV study to look at daily prevention pill* [Online]. Available: <http://www.pinknews.co.uk/2011/04/20/gay-hiv-study-to-look-at-daily-prevention-pill/> [Accessed 01 March 2015].
- PREP ACCESS. (2014) *Statement on PrEP from community organisations working on HIV prevention* [Online]. Available: <http://www.prepaccess.org.uk/> [Accessed 24 November 2015].
- PROJECT GEL. (2015) *Project Gel - Guys Experiencing Lube* [Online]. Available: <http://microbicides.us/> [Accessed 23 November 2015].
- REID, D., WEATHERBURN, P. & HICKSON, F. (2002) Know the score: findings from the national gay men's sex survey 2001. London, UK: Sigma Research.

- REY, D., DEN DIANE, M. & MOATTI, J. (2000) Post-exposure prophylaxis after occupational exposure to HIV: overview of the policies implemented in 27 European countries. *AIDS Care*, 12, 263-5.
- RIESSMAN, C. (ed.) (1993) *Narrative Analysis*, Newbury Park, CA, USA: Sage.
- RODRIGUEZ, M. (2014) We must end PrEP segregation. *Advocate*.
- SABERI, P., GAMAREL, K., NEILANDS, T. & ET AL (2012) Ambiguity, ambivalence and apprehensions of taking HIV-1 pre-exposure prophylaxis among male couples in San Francisco: a mixed methods study. *PLoS ONE*, 7.
- SELECT COMMITTEE ON HIV AND AIDS IN THE UNITED KINGDOM (2011) No vaccine, no cure: HIV and AIDS in the United Kingdom - 1st Report of Session 2010-12. London: House of Lords.
- SIGMA RESEARCH (2011) The Sigma Panel Insight Blast 6: Prospective Attitudes to HIV Pre-Exposure Prophylaxis (PrEP) London.
- SLOVIC, P. (2000) *The Perception of Risk*, London., Earthscan.
- SMIT, P., BRADY, M., CARTER, M. & ET AL (2012) HIV-related stigma within gay communities: A literature review. *AIDS Care*, 24, 405-412.
- SMITH, J. & OSBORN, M. (2003) Interpretive Phenomenological Analysis. In: SMITH, J. (ed.) *Qualitative psychology: A practical guide to research methods*. London: Sage.
- SPREEN, W., WILLIAMS, P., MARGOLIS, D. & ET AL (2013) First study of repeat dose co-administration of GSK 1265744 and TMC278 long-acting parenteral nanosuspensions: pharmacokinetics, safety and tolerability in healthy adults. *7th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention*. Kuala Lumpur, Malaysia.
- STANGL, A., BRADY, L. & FRITZ, K. (2012) Measuring HIV stigma and discrimination. *STRIVE Technical Brief*. International Centre for Research on Women. Washington, DC.
- STERN, M. (2014a) Even if HIV-preventing drugs increased unprotected sex, they'd still be worth taking. *Slate Magazine*.
- STERN, M. (2014b) There is a daily pill that prevents HIV. Gay men should take it. *Slate Magazine*.
- STRAUSS, A. L. & CORBIN, J. (1998) *Basics of Qualitative Research: Grounded Theory Procedures and Techniques*. London., Sage Publishers.
- SULLIVAN, P., CARBALLO-DIEGUEZ, A., COATES, T. & ET AL (2012) Successes and challenges of HIV prevention in men who have sex with men. *The Lancet*, 380, 388-399.
- TATOUD, R. (2011) *HIV combination prevention: ingredients and recipes for a success* [Online]. Available: <http://www.incidence0.org/2011/05/10/combo-hiv-prevention-ingredients-recipes-for-a-success/> [Accessed 4 October 2011.]
- TERRENCE HIGGINS TRUST. (2006) *Post-Exposure Prophylaxis micro-site* [Online]. Terrence Higgins Trust. Available: <http://www.pep.chapsonline.org.uk/> [Accessed 15 Jan 2015].
- THE BODY PRO. (2012) *Newspapers Examine Concerns Surrounding Possible FDA Approval of Truvada for PrEP* [Online]. Available: <http://www.thebodypro.com/content/67145/newspapers-examine-concerns-surrounding-possible-f.html> [Accessed 5 June 2015].
- THNG, C. (2012) Acceptability of HIV pre-exposure prophylaxis (PrEP) and associated risk compensation in men who have sex with men (MSM)

- accessing GU services. *Annual Conference of the British HIV Association*. Birmingham.
- TULLER, R. (2013) A resisted pill to prevent HIV. *The New York Times*, 30 December 2013.
- UNAIDS (2010) Combination HIV Prevention: Tailoring and Coordinating Biomedical, Behavioural and Structural Strategies to Reduce New HIV Infections.
- UNAIDS (2011) Groundbreaking trial results confirm HIV treatment prevents transmission of HIV.
- VAN DAMME, L. (2007) Phase III trial of 6% cellulose sulfate (CS) gel for the prevention of HIV transmission. *Fourth International AIDS Society Conference on HIV Treatment and Pathogenesis*. Sydney.
- WEATHERBURN, P., ANDERSON, W., REID, D. & ET AL (2002) What do you need? Findings from a national survey of people living with HIV. London, UK: Sigma Research.
- WEATHERBURN, P., HICKSON, F. & REID, D. (2003) Net benefits: gay men's use of the internet and other settings where HIV prevention occurs. London, UK: Sigma Research.
- WEATHERBURN, P., KEOGH, P., REID, D. & ET AL (2009) What do you need? 2007-2008. Findings from a national survey of people with diagnosed HIV. Sigma Research.
- WHELOCK, A., EISINGERICH, A., GOMEZ, G. & ET AL (2012) Views of policymakers, healthcare workers and NGOs on HIV pre-exposure prophylaxis (PrEP): a multinational qualitative study. *BMJ Open*, 2.
- WILLIAMSON, L., DODDS, J., MERCEY, D. & ET AL (2008) Sexual risk behaviour and knowledge of HIV status among community samples of gay men in the UK. *AIDS*, 22, 1063-1070.
- WITZEL, T., MELENDEZ-TORRES, G., HICKSON, F. & ET AL (2015) HIV testing and preferences for future tests among gay men, bisexual men and other MSM in England.
- WORLD HEALTH ORGANISATION (2012) Guidance on pre-exposure oral prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV: recommendations for use in the context of demonstration projects. Geneva, Switzerland: World Health Organisation.
- YEUNG, B. (2012) Truvada, Foster City drugmaker's HIV prevention pill, draws concern from experts. *Huffington Post*, 30 January 2012.
- YIN, Z., AE., B., HUGHES, G. & ET AL (2014) *HIV in the United Kingdom 2014 Report: data to end 2013*. London, UK: Public Health England.
- YOUNG, I., FLOWERS, P. & MCDAID, L. (2014) Barriers to uptake and use of pre-exposure prophylaxis (PrEP) among communities most affected by HIV in the UK: findings from a qualitative study in Scotland. *BMJ Open*, 4.
- YOUNG, I., LI, J. & MCDAID, L. (2013) Awareness and willingness to use HIV pre-exposure prophylaxis amongst gay and bisexual men in Scotland: implications for biomedical HIV prevention. *PLoS One*, 8, e64038.
- YOUNG, I. & MCDAID, L. (2014) How acceptable are antiretrovirals for the prevention of sexually transmitted HIV?: A review of research on the acceptability of oral pre-exposure prophylaxis and treatment as prevention. *AIDS Behaviour*, 18, 195-216.

Appendix 1

Dear Sigma Research mailing-list member -

My name is Will Nutland and I'm working with the Sigma Research group at the London School of Hygiene & Tropical Medicine. I am contacting you because you are a member of the Sigma Research mailing list and previously indicated you might like to hear about new research that we're doing.

I am currently recruiting men in London to take part in one-to-one discussions or focus groups on a research project exploring the acceptability of using HIV medication to prevent HIV.

It would be great to speak to you if:

YOU are a man between the ages of 18-45 who lives in London
AND You have had an HIV negative test in the last 12 months
AND You have had anal sex with another man *without a condom* since that last HIV test
AND that sex was with someone you either KNEW was HIV positive or whose HIV status you weren't sure of

If you meet these criteria it would be great to hear from you. Please follow this link for more details:

<https://www.surveymonkey.com/s/prepaceptability>

There's a short survey to complete and you can let me know the best way of getting in touch if you decide you'd like to take part. The survey is confidential and will not collect your I-P address.

Thank you in advance for your help.

Will Nutland

Appendix 2

ONLINE QUESTIONNAIRE COPY

Please give your contact details and answer a few questions about yourself. This will help to determine if you meet the criteria to participate in the research and to ensure we have a wide cross section of men involved.

If you choose not to give your real name, please give a name you will recognize. Please also give a contact telephone number and an email address. The researcher will contact you shortly if you are selected to participate. We will NOT leave any message on your answering service unless you tick 'yes'. These details will never be used for any other purpose.

How old are you?

How old are you?

Under 18 (End)

Over 45 (End)

Are you ...?

Female (End)

Male

Which of the options below best describes how you think of yourself?

Heterosexual (straight)

Gay

Bisexual

Other

Are you a Trans-man? (Transexual / Transgender – someone who has changed or intends to change their biological sex)

No

Yes

Do you currently live in London?

Yes

No (End)

What is your ethnic group?

WHITE: British

WHITE: Irish

WHITE: Any other white background

BLACK: African

BLACK: Caribbean

BLACK: Any other Black background

MIXED: White and Black Caribbean

MIXED: White and Black African
MIXED: White and Asian
MIXED: Any other background
ASIAN: Indian
ASIAN: Pakistani
ASIAN: Bangladeshi
ASIAN: Chinese
ASIAN: Any other Asian background
OTHER: Arab
OTHER: Any other ethnic group

What is your highest educational qualification?

I have no educational qualifications
Primary education only (left school at 11 or 12)
O-levels/ GCSEs/ CSEs or equivalent (left school at age 16)
A-levels or equivalent (left school at age 18)
University degree or higher
Other, such as vocational or professional qualifications

In the last 12 months have you:

Had NO sex at all (End)
Had sex ONLY with women (End)
Had sex with men AND women (Go to Question X)
Had sex ONLY with men (Go to Question X)

Have you EVER received an HIV test result?

Yes (go to Question X)
No (End)

Have you:

Received an HIV test result that was POSITIVE (End)
Tested for HIV but don't know/remember the results (End)
Received an HIV test result that was NEGATIVE (go to Question X)

Have you:

Received an HIV test that was NEGATIVE more than 12 months ago (End)
Received an HIV test that was NEGATIVE in the last 12 months (go to Question X)

When did you receive those test results?

INSERT DATE

The following questions relate to the types of sex you have had. We're interested in the ANAL intercourse you've had. By this we mean fucking - top or bottom or both – with a penis in to an anus. Please do NOT count anal sex using fingers, fists, dildos or sex-toys.

Since receiving that last NEGATIVE HIV test result have you had:

NO sex (End)

No ANAL intercourse (End)

Anal intercourse ONLY with condoms (End)

Anal intercourse WITHOUT condoms (even if only once) (go to Question X)

Tick as many as apply:

Anal intercourse WITHOUT condoms with a man I KNEW to be HIV negative

Anal intercourse WITHOUT condoms with a man I KNEW to be HIV positive

Anal intercourse WITHOUT condoms with a man whose HIV status I did not know or whose HIV status was NOT discussed

Your First name:

Your First name:

Would you like to give your email, telephone number or both?

Tick as many as apply

Email address

Telephone number

<Are you happy for a message to be left on this telephone number?>

<End> Thank you for taking part in the questionnaire. One or more of your responses means that you do not fit the criteria for participation in this study.

Thank you for completing the questionnaire. The researcher will be in touch with you to discuss what happens next.



PRE-INTERVIEW PARTICIPANT INFORMATION SHEET

The acceptability of pre-exposure prophylaxis as an HIV prevention technology among men who have sex with men in London

Will Nutland

London School of Hygiene and Tropical Medicine

Thank you for considering taking part in this study. Before agreeing to take part it is important that you read and understand the information on this sheet. If any parts of it are unclear or you have any further questions, please ask the researcher. Once you have read the sheet, you will be asked to sign a **CONSENT FORM** if you decide to participate.

Why are we doing this study?

This study is part of a research project exploring the acceptability of using HIV medication to prevent new HIV infections in men who have sex with men in London. The findings will be used to help inform future HIV prevention services in London. The experiences of the kind of sex you have and your thoughts on taking HIV medication to prevent HIV are important for the research. The study has been given ethics approval from the Ethics Committee of the London School of Hygiene and Tropical Medicine.

What will participation involve?

- **One-to-one interviews** with men. During the interviews men will be asked about the types of sex they have had recently and what they think about using HIV medication to prevent HIV. The interviews will take up to 90 minutes. The interview will be audio-recorded (see below about confidentiality).

Is my participation confidential?

Yes. Everything that is said in the interview remains confidential. The researcher will not reveal your name, or any other information that might identify you to any other person. We will keep your first name, contact telephone number and email address on file until after the interview or focus-group and this will be destroyed after participation.

What happens after the interview?

All interviews will be audio-recorded to make sure everything that you say is captured. The recordings will be kept in secure, password protected files. Afterwards, the

researcher will listen to the recordings and type up everything that was said. We will not type up any details that might identify you (such as names or place names) and the audio-files will be destroyed once they have been typed-up.

At a later stage the researcher will look at what is interesting or important from the interviews and groups and will write up a report about it. The report will be available for anyone to read but there will be nothing in it that could identify you and there will be no mention that you took part in the study. Any direct quotations from participants will be used anonymously. Findings from the report might also be reported at conferences, in academic papers and in the media.

Can I change my mind about taking part?

Yes. If at any time before the date of an interview you decide you do not want to take part then you can let the researcher know. At any time during an interview you can ask for the interview to stop without having to give a reason. *Your participation is entirely voluntary and you can withdraw at any time from the study.*

What happens next?

If you agree to participate in the study, please read and sign the **CONSENT FORM** provided by the researcher. At the end of the interview the researcher will provide you with further information about using HIV medications to prevent HIV. The information sheet will also provide you with details of where to get support and information about HIV prevention and sexual health.

Will Nutland

Will.nutland@lshtm.ac.uk

Appendix 4

Consent form

I understand that participation in the interview is voluntary

I can withdraw from the interview at any time and do not have to give a reason

I agree to the interview being audio-recorded. I understand that these digital recordings will be stored securely and not shared without anyone outside the research team (the research and his supervisor). All recordings will be safely destroyed once they have been transcribed (typed up).

I understand that the results of this interview will be used as part of a research study. Although the research report may contain quotes from this interview (along with quotes from other individual interviews being undertaken as part of this study), no-one will be able to identify me from these quotes.

I understand that the results of this research may also be published in academic papers, presented at conferences or discussed in the media and they may contain quotes as above. No-one will be able to identify me or any other members of the group from these quotes.

I confirm that I have had the opportunity to ask any further questions about this research study and any questions have been answered.

I confirm that I am aged 18 or over, I have read and understood the information above and DO want to take part in this interview.

Signature

Date

OR I have read and understood the above information and DO NOT want to take part

Appendix 5

PrEP acceptability topic guide

I'm Will – I study at LSHTM, which is part of the University of London. As you know, I'm doing research at the moment to find out views about the acceptability of using HIV drugs to prevent HIV infection.

Men who have sex with men who live in London have been invited to take part in this research. I'm interested in the views of men who do not have HIV and who have had unprotected anal sex with a man who either has HIV or whose HIV status he or you do not know. I'm interested in interviewing men who have had this kind of sex in the last year and since their last negative HIV test.

The interview will be very informal and will take between an hour to ninety minutes. I'd like to record the interview to make sure I don't miss anything. After the interview, the recording will be given a code and will be transcribed. After the research is complete, the recording will be destroyed. Everything we talk about will be confidential and anonymous. If there are any questions you would prefer not to answer that is no problem. If you want to stop the interview at any time please let me know – you do not have to give a reason.

Before we start, is there anything you'd like to ask about the research?

Answer any questions, go through the consent form.

Could you start by telling me a bit about where you socialise?

Do you use the gay scene?

What types of places?

Where do you meet other men (for sex?)

You said in your response to the online survey that your last HIV test was X months ago. Is that right? Can you tell me about the type of sex you've had since your last HIV test?

I'm interested in the unprotected anal intercourse you have had.

Was it a one off? With a regular partner? Planned? Did it 'just happen?'. Did you talk with the other man/men about it before or after?

When you've had UAI how have you managed or thought about managing any risk?

Modality? Withdrawal? PEP? TasP?

In this research, I'm interested in finding out more about if and how men might use PrEP.

- Can you tell me what you have heard about PrEP?

- Where did you get this information from?

International trials have shown that when someone who doesn't have HIV takes a DAILY oral pill of PrEP it can reduce the chance of HIV transmission by over 90%, when the pills are taken properly.

- What do you think about all of this?
- Is this something you had heard about?
- Is this something you think you would take if it became available here?
- What kind of issues would you consider before making that choice?
Cost? Effectiveness? Clinic visits? Side effects?
- In what kind of situations might you consider using it?

What about if the pill could be taken before sex, rather than every day?

- Would that change things for you?
Adherence? Convenience? Fewer side-effects? Cheaper?

Research is also being done that looks into providing the drug in a monthly or 3 monthly injection and in a gel or foam that is inserted in the rectum before sex.

- Would these be more acceptable for you?
Usability? Side-effects? Effectiveness? Adherence. Discretion of use.

What about other men you know? What do you think they would make of PrEP?

- Do you think men you know might use it?
- In what kind of circumstances?
- Do you think men you know would talk about using PrEP if they took it?
Stigma? Discrimination? Taboo?

If you were taking PrEP, how do you think other men would respond?

- What would it mean for negotiating the kind of sex you have with these men?
- Do you think you'd tell them?

And if you weren't using PrEP, how would you feel about having sex with another man who was using it?

How do you think PrEP might be viewed more broadly?

- By 'community'
- Wider society – media, medical profession

For PrEP to be used by men, it needs to be acceptable to men.

- What would make PrEP acceptable to you?
- What does being 'acceptable' mean for you with regards to PrEP?

Is there anything else you want to say about everything we've talked about today?

Clarifying questions. Provide information sheet.

Appendix 6

iPREX study

2,500 men who have sex with men

Peru, Ecuador, Brazil, USA, South Africa and Thailand

Half of the men given a placebo

Half of the men given a daily oral pill of Truvada

In the drug arm – 44% lower rate of HIV infection than in the placebo arm

In men in the drug arm who were most treatment adherent – 92% lower rate of HIV infection than in those without a detectable level of drugs

No major side effects

None of participants developed resistance to drugs

CAPRISA study

889 sexually active women in South Africa

Half of the women received a placebo gel

Half of the women received a gel with 1% tenofovir

All women were asked to apply the gel vaginally within 12 hours before sex and within 12 hours after

In the trial arm – HIV infection fell by about a half compared with women in the placebo arm

Women who used the gel consistently and as required were less likely to get HIV than women who used it less consistently

SSAT 040 trial

27 women, 6 men – all HIV negative

Injectable once a month formulation of rilpivirine

Maintained high enough drug levels to provide sufficient protection against HIV infection

Few side effects – localised swelling and tenderness

Appendix 7

Post interview participant Information Sheet

Thank you for being part of this study, being undertaken as a research project at the London School of Hygiene and Tropical Medicine.

The HIV prevention medication we discussed today is called **pre-exposure prophylaxis** or **PrEP**. There has been a great deal of research undertaken about PrEP in recent years, with many new studies in development.

Although PrEP is currently about to be licensed in the USA, it is **NOT** licensed for HIV prevention in the UK at this time. In the USA it will be available as a one-a-day pill. It is currently not available – outside of clinical trials – in the other formats we discussed today (such as injectable PrEP or as a rectal gel or foam). More clinical research into these methods of PrEP is needed.

If PrEP becomes more widely available across the world, it will need to be prescribed correctly and regular medical check-ups will be likely. In some parts of the world, people who want PrEP might have to pay for it themselves.

Anyone being prescribed PrEP will need to take it as directed by a medical expert and will need to have regular HIV tests to ensure they have not become infected.

There are still many things we do not know about PrEP. For example, the long-term health effects of taking PrEP are unclear. In addition, PrEP will not prevent other sexually transmitted infections, including more serious ones such as syphilis and hepatitis B or C.

If you are in a relationship with, or having sex with someone who has HIV, it is important that you **DO NOT** share their HIV medications to try to prevent getting HIV. The doses of medication given in PrEP need to be right, and not all HIV medications have been tested for use to prevent HIV. Sharing someone else's HIV medication could be dangerous for you, and the other people you have sex with.

PrEP is different from **PEP (post-exposure prophylaxis)**. PEP is used as an emergency HIV prevention course of medication when someone who doesn't have HIV knows they have been exposed to HIV (for example, if a condom broke or if condoms weren't used). PEP has been available for several years and is widely available for **FREE** from sexual health clinics or Accident and Emergency centres. It must be taken as soon after exposure to HIV as possible and is a month-long course of tablets. For more information on PEP visit - <http://www.tht.org.uk/sexual-health/HIV-STIs/HIV-AIDS/Post-exposure-prophylaxis>

If you are worried or concerned about your sexual health or risk taking you can discuss this with a doctor or health advisor at a free sexual health clinic. They can discuss the options of help and support available to you. You can visit any NHS sexual health clinic

you want to for free. To find a clinic close to you visit – <http://www.tht.org.uk/sexual-health/Clinics-and-Services/Local-services-and-clinics>

You can also find out more about HIV prevention and sexual health by visiting the website of Terrence Higgins Trust – www.tht.org.uk or by calling THT Direct on 0808 802 1221

If you want to find out more about developments in PrEP research, you can visit, or subscribe to Aids Map for free (search for 'PrEP' in their search engine) - www.aidsmap.com

If you would like to be sent a summary of the final findings of the research you took part in today, please email will.nutland@lshtm.ac.uk and ask for a copy to be emailed to you.