Facilitators and barriers to active recall for HIV and STI testing of MSM at high risk of HIV infection in genitourinary medicine clinics

A thesis submitted for the degree of MD(Res)

Monica Desai

Research Department of Infection and Population Health

University College London (UCL)

2015

Declarations

I, Monica Desai, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed,

Abstract

Reminders have been successfully used in healthcare to improve reattendance rates but evidence for their effectiveness in sexual health remains unknown.

A programme of studies explored the effectiveness of, and drivers and barriers to active recall reminders in increasing reattendance/re-testing rates for HIV/STIs among men who have sex with men (MSM), underpinned by the Theory of Planned Behaviour.

The systematic literature review suggested efficacy of reminders in increasing reattendance/re-testing rates for HIV/STIs, but was unable to determine which modality of reminder was most effective.

In a service evaluation, text SMS reminders were offered to MSM who reported unprotected anal sex in the past three months. The evaluation was unable to demonstrate an increase in reattendance rates; however concurrent health promotion may have counfounded the results.

To explore preferred type and frequency of reminder, and attitudes to HIV/STI testing and reminders, 406 MSM attending a sexual health clinic were surveyed. Preferring SMS reminders, liking being reminded to check health status, not being concerned about the confidentiality of reminders and preferring to have a reminder to test were associated with intention to reattend in multivariable analysis, but not with documented reattendance. Concern about potential stigma of being sent a reminder was associated with reduced intention to reattend.

Contextual factors influencing these attitudes to testing and reminders were explored in 16 interviews. Drivers for testing included easy access to testing facilities and the influence of peers or a regular male partner. Conversely, barriers included conflict with being in a trusting relationship, difficulty of accessing tests, fear/embarrassment and concerns about wasting resources. Key themes in responding to reminders included convenience and confidentiality of the reminder, control over receipt and response to the reminder, and reminder persistence.

These findings will inform HIV testing recall policies and provides further support for preference for SMS reminders.

Table of Contents

List of tables

List of figures

Table of abbreviations

ARV	Antiretroviral
BASHH	British Association for Sexual Health and HIV
CI	Confidence interval
CAQDAS	Computer-assisted qualitative data analysis software
CMP	Casual male partner
EPR	Electronic Patient Record
GP	General Practitioner
GATE	Graphical appraisal tool for epidemiological studies
GUM	Genitourinary Medicine
GUMCAD	Genitourinary Medicine Activity Database
HIV	Human Immunodeficiency Virus
IDI	In-depth interview
IDU	Injecting Drug User
LGV	Lymphogranuloma venereum
MDG	Millennium Development Goals
MSM	Men who have sex with other men
NATSAL	National Survey of Sexual Attitudes and Lifestyles
NHBS	National HIV Behavioural Surveillance System
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PEPSE	Post-exposure prophylaxis for HIV after sexual exposure
PrEP	Pre-exposure prophylaxis
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
OR	Odds ratio
QALY	Quality Adjusted Life Year
RCT	Randomised controlled trial
RITA	Recent Infection Testing Algorithm
RMP	Regular Male Partner
ROC	Receiver Operating Curve

SMS	Short Message Service	
START study	Strategic Timing of Antiretroviral Treatment	16
STI	Sexually Transmitted Infections	
TPB	Theory of Planned Behaviour	
TRA	Theory of Reasoned Action	
TTM	Trans-Theoretical model	
UAI	Unprotected Anal Intercourse	
UK	United Kingdom	
WHO	World Health Organisation	

Chapter 1   Introduction

1.1 **Background**

In England, men who have sex with men (MSM) are the population most likely to acquire HIV sexually(1). An estimated 2,470 MSM in England acquired HIV infection in 2013(1), a number which has remained relatively constant in recent years despite increased HIV testing in this population and earlier initiation of antiretroviral therapy(2).

National guidelines in England recommend testing MSM at high risk of sexually transmitted infections (STIs) every three months for HIV and STIs(3). Modelling studies suggest that three-monthly testing is cost saving and could reduce the number of new HIV infections as early knowledge of HIV status and access to risk reduction interventions can reduce onwards transmission of infection (4, 5). Despite this, cross-sectional survey data suggest that fewer than a quarter of MSM in England and Scotland have four or more HIV tests per year(6), despite a 3.7 fold increase in HIV testing in MSM between 2001 and 2010(2).

Reminders in other forms of healthcare, such as immunizations, have been shown to improve attendance and re-attendance rates(7, 8). National guidance recommends use of reminders to encourage retesting of MSM who have been diagnosed with a bacterial STI, but only a quarter of sexual health clinics have a recall system in place(9).

If reminders are to be used more widely in sexual health, healthcare providers need to know which is the most effective approach to increase reattendance/re-testing rates before widespread implementation.

This thesis examines the effectiveness of reminders for HIV and STI testing in increasing reattendance/re-testing rates for MSM. It also explores the drivers and barriers to reattendance/re-testing for MSM if sent a reminder, and the

preferred reminder type and frequency. It uses several different methods to explore this aim, which are discussed in more detail below.

1.2 Structure of thesis

The thesis describes a programme of studies that examine the effectiveness of and drivers and barriers to active recall in increasing reattendance/re-testing rates.

Chapter 2 provides the contextual background to the thesis. The whole thesis is underpinned by a conceptual framework based on Ajzen's Theory of Planned Behaviour(10). This framework is described in chapter 2.

Chapter 3 describes the overarching research question and the objectives of each of the studies within the programme of work. The methodologies that were used and their limitations are discussed.

The systematic review of the literature in chapter 4 considers the available evidence on the use of reminders in sexual health to increase reattendance/re-testing rates for HIV/STIs, both overall and by modality (e.g. SMS, phone call reminder, email etc).

The effectiveness of active recall reminders in increasing retesting for HIV/STIs is tested by evaluation of a service development which was implemented during the project. The results of this are presented in chapter 5, adding to the literature available on active recall for reattendance/re-testing for HIV/STIs. A service evaluation design was used in preference to a randomised controlled trial (RCT) design for several reasons. Firstly, the clinic setting already used text message reminders to recall MSM who were diagnosed with an acute bacterial STI; therefore a RCT was not feasible. A service development expanding the use of these reminders to MSM who reported unprotected anal sex (UAI) with casual male partners (CMP) in the past three months was the preferred intervention in this setting. Using the Programme Science approach described in chapter 2, this design also allowed the drivers and barriers to active recall to be explored.

To explore possible reasons for differences in findings between active recall studies in increasing reattendance/re-testing for HIV/STIs, the drivers and barriers for active recall are explored using a mixed methods approach. Firstly a questionnaire survey was conducted to examine the factors and attitudes associated with intention to respond to active recall reminders. The results are presented in Chapter 6. The questionnaire survey was informed by the results of the systematic literature review from chapter 4.

These attitudes revealed by the questionnaire survey are explored in more detail within the in-depth interviews, which are presented in chapter 7.

The results of each of the studies contribute to modifying the conceptual framework that was proposed in chapter 2 and provides a final conceptual model at the end of the thesis in chapter 8.

The findings of the thesis are drawn together in the final chapter (chapter 8) to suggest lessons for policy, service development and avenues for further research.

1.3 Role of the candidate

My MDRes advisory panel consisted of my primary supervisor, Dr Richard Gilson, and my secondary supervisors, Dr Anthony Nardone, Dr Fiona Burns and Dr Danielle Mercey.

I conceived the idea for the programme of studies described in this thesis. I was responsible for study design, survey design and development, instrument testing/validation, cognitive and in-depth interview design and development of interview tools, project management, application to funders, ethics committee application and attendance at ethics review, data management, cleaning and analyses and writing the first drafts of presentations and publications. I was supported in the study conception, development of study protocol and materials by the advisory panel. I was supported in project management by a research nurse, Asma Ashraf. A research assistant, Damiola Otiko, was employed to enter survey data into the study database. I was principal investigator for the study, and Dr Gilson also met with the research teams at

Mortimer Market to monitor progress of the study and discuss problems and solutions where necessary. I was trained in and performed the cognitive and in-depth interviews. I undertook all data analyses relating to the study, both quantitative and qualitative, with statistical support from Dr Andrew Copas and Dr Pamela Muniina. I was supported by Dr Sarah Woodhall from Public Health England in reviewing and assessing the quality of the studies included in the systematic literature review.

Chapter 2 Background and conceptual model

2.1 Introduction

The overall aim of this thesis is to explore the effectiveness of active recall reminders for testing for HIV and STIs among men who have sex with men (MSM) and the drivers and barriers to reattendance/re-testing if sent a reminder.

The main population focus of this thesis is MSM in England. This background chapter places the HIV epidemic among MSM in England in the context of the global and national epidemics.

HIV testing is one of the tools available in the HIV prevention toolkit, and this thesis discusses the rationale for frequent testing. The intervention discussed in the thesis, active recall reminders, relies upon recipients having engaged with sexual health services previously. Therefore, this chapter also places the intervention in the context of national guidelines and discusses the rationale for the intervention. It acknowledges the limitations of active recall reminders in not being able to target those who have never engaged with sexual health services.

Finally, the chapter outlines the basis for the conceptual framework and discusses the reasons for choosing the Theory of Planned Behaviour as the theoretical framework for the work. It also outlines the concept of Programme Science which underpins the methodological process of the programme of work.

2.2 The Global HIV epidemic

In September 2000, world leaders met at the United Nations headquarters to define eight pledges that they committed to help achieve by 2015. Millennium development goal (MDG) six pledged to combat HIV/AIDS. Despite the criticisms leveled against it, one achievement of this MDG was to highlight the

historic impact of HIV/AIDS globally. Since the earliest cases in the 1980s, more than 30 million people have died from HIV-related complications.

Globally, it is estimated that 35 million (95% credible interval 33.2-37.2 million) people were living with human immunodeficiency virus (HIV) in 2013(11). This represents an increase from previous years, driven by continued new HIV infections and an increase in survival as a result of expansion in coverage of antiretroviral treatment for those infected with HIV. The epidemic is concentrated in Sub-Saharan Africa, where two-thirds of all people living with HIV reside. The epidemic is complex, driven by different factors in different regions. Broadly, in low-income countries, the epidemic is driven mainly by heterosexual transmission and in higher-income countries by other risk behaviours, such as sex between men.

The number of new infections of HIV declined by one third in 2013 (2.1 million (95% credible interval 1.9-2.4)) compared to 2001 (3.4 million (95% credible interval 3.1-3.7))(11, 12). In areas with generalised epidemics, this has been due in part to earlier diagnosis and treatment, changes in behaviour(13, 14) and behavioural and biomedical interventions(15). Earlier diagnosis and treatment has also led to a decline in the numbers of AIDS deaths from 2.3 (95% credible interval 2.1-2.6) million in 2005 to 1.5 (95% credible interval 1.4-1.7) million in 2013(11, 12). Antiretroviral treatment (ART) has enabled HIV to be transformed from a terminal into a chronic illness. Ten low- and middle-income countries now have a universal access system with ART coverage of at least 80% for those who need it(16). However, some regions, such as the Middle East, North Africa and Eastern Europe, have seen the numbers of new infections increase, particularly among at-risk populations.

However several challenges remain in achieving the series of elimination commitments and targets set for 2015 by the MDG and the UN High-Level Meeting on HIV and AIDS in 2011. For example, sexual transmission of HIV has been halved in 26 countries around the world but in many other countries the decline has been slower. Some countries in sub-Saharan Africa have seen an increase in risk behaviours with reported increases in partner numbers and decline in condom use(12). Antiretroviral coverage of pregnant

women has increased to 62% in 2012, yet there are still gaps in linkage to care and integrated approaches to care and variability in coverage of pregnant women compared to other adults with antiretrovirals(12, 17, 18).

The HIV prevention toolkit is expanding, with behavioural interventions being strengthened, biomedical interventions such as male circumcision being scaled up, and newer interventions such as treatment as prevention (TasP) and pre-exposure prophylaxis (PrEP) being tested for effectiveness in demonstration projects. Antiretroviral coverage has increased(12) with an estimated11.7 million people in low- and middle-income countries receiving antiretroviral treatment in 2013(11). However, there is a long way to go to meet the aims of the WHO 2013 treatment guidelines(19); currently only 34% (95% credible interval 32-37%) of the 28.3 million people in low- and middle-income countries who are eligible for antiretroviral treatment under WHO 2013 guidelines receive it(12).

HIV transmission is influenced by social, political and economic drivers. Any intervention to abate the epidemic needs to tackle not just the biological transmission pathway, but also the complex and evolving systems that interplay with it.

2.3 HIV in the UK

In 2013, an estimated 107,800 (95% credible interval 101,600-115,800) people were living with HIV in the UK, with an overall prevalence of 2.8 per 1,000 population aged 15-59 years(1) (table 1).

Men who have sex with men and black-African men and women remain disproportionately affected by HIV infection with prevalences of 59 (95% credible interval (CI) 52, 68), 41 (95% CI 35, 49) and 71 (95% CI 63, 81) per 1,000 population respectively.

Table 1: Estimated number of people living with HIV (both diagnosed and undiagnosed): United Kingdom, 2013 (taken from HIV annual report 2014, PHE)(1)

Exposure category			Total HIV infection (credible interval)	% undiagnosed (credible interval)	HIV prevalence per 1,000 population (credible interval)
Men who have sex with men			43,501 (40,210-48,160)	16% (10,25%)	59 (52, 68)
People who inject drugs			2,353 (2,131, 2,563)	10% (6, 16%)	6.7 (5.5, 8.3)
Heterosexuals			59,490 (54,690, 66,040)	31% (25, 38%)	1.6 (1.5, 1.8)
	Men		23,980 (21,610, 27,410)	34% (27, 42%)	3.7 (3.5, 4.0)
		Black-African ethnicity	13,640 (11,750, 16,680)	38% (29, 50%)	41 (35, 49)
		Non-black-African ethnicity	10,230 (9,061, 12,250)	27% (18, 39%)	0.6 (0.5, 0.7)
	Women		35,450 (32,660,28,870)	29% (23, 36%)	1.9 (1.7, 2.0)
		Black-African ethnicity	25,060 (22,360, 28,870)	31% (23, 40%)	71 (63, 81)
		Non black-African ethnicity	10,340 (9,438, 11,670)	23% (16, 32%)	0.6 (0.5, 0.6)
Total			107,800 (101,600, 115,800)	24% (20, 29%)	2.8 (2.7, 3.0)

Effective anti-retroviral therapies have transformed HIV into a chronic infection and people living with diagnosed HIV in the UK have near-normal life expectancy. Consequently, the number of people living with diagnosed HIV has increased year on year (figure 1).

Figure 1: Annual number of people living with diagnosed HIV infection and newly diagnosed with HIV: United Kingdom, 1980-2011 (taken from HIV Annual Report 2012, HPA)(20)
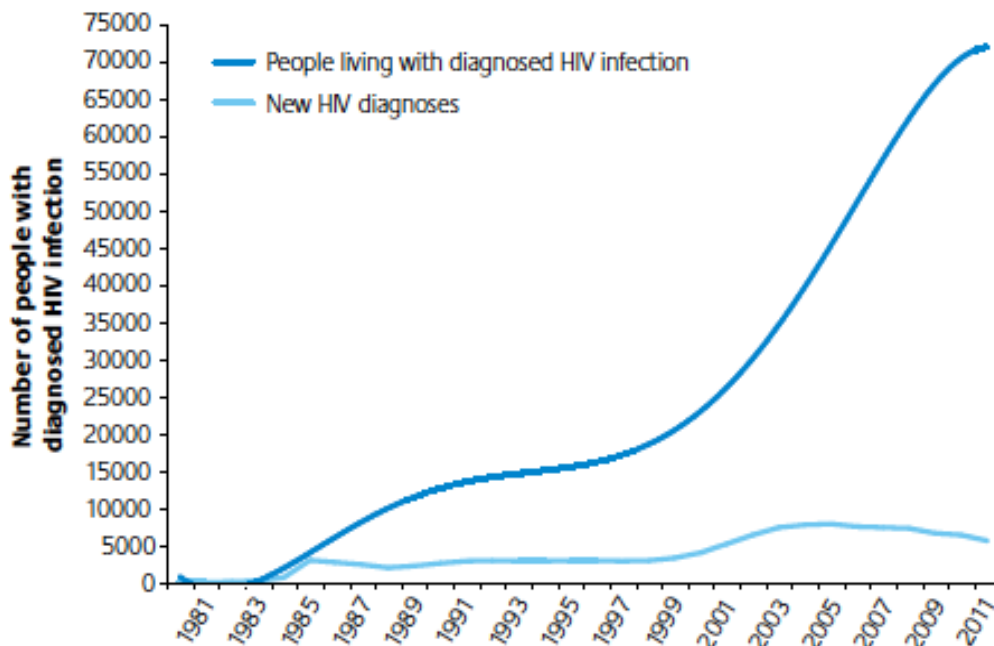
The numbers of new HIV diagnoses in the UK increased rapidly in the late 1990s and early 2000s to peak in 2005, but has since declined. In the main this is due to a decrease in the number of diagnoses reported among heterosexuals born in a high prevalence country (figure 2). In 2013, 6,000 people were newly diagnosed with HIV(21), a 21% decline from the peak in 2005(20).

Figure 2: Annual new HIV and AIDS diagnoses and deaths: United Kingdom, 1981-2013 (taken from HIV annual report 2014, PHE)(1)
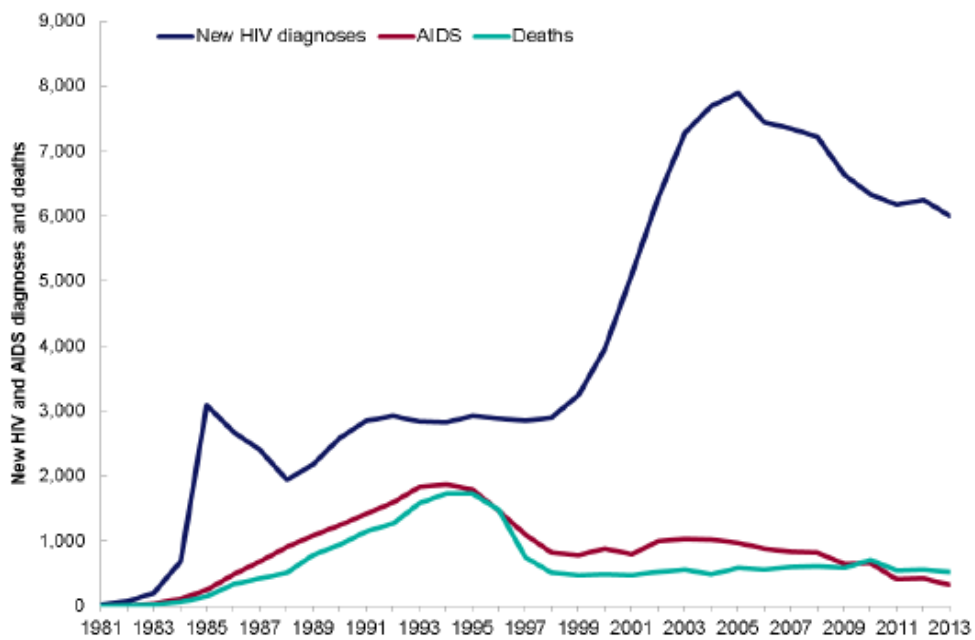
However, among MSM, numbers of new diagnoses of HIV continue to rise year on year (figure 3) and has overtaken the numbers among heterosexuals since 2006.

Figure 3: New HIV diagnoses by exposure group: United Kingdom 2002-2011 (taken from HIV annual report 2012, HPA)(20)
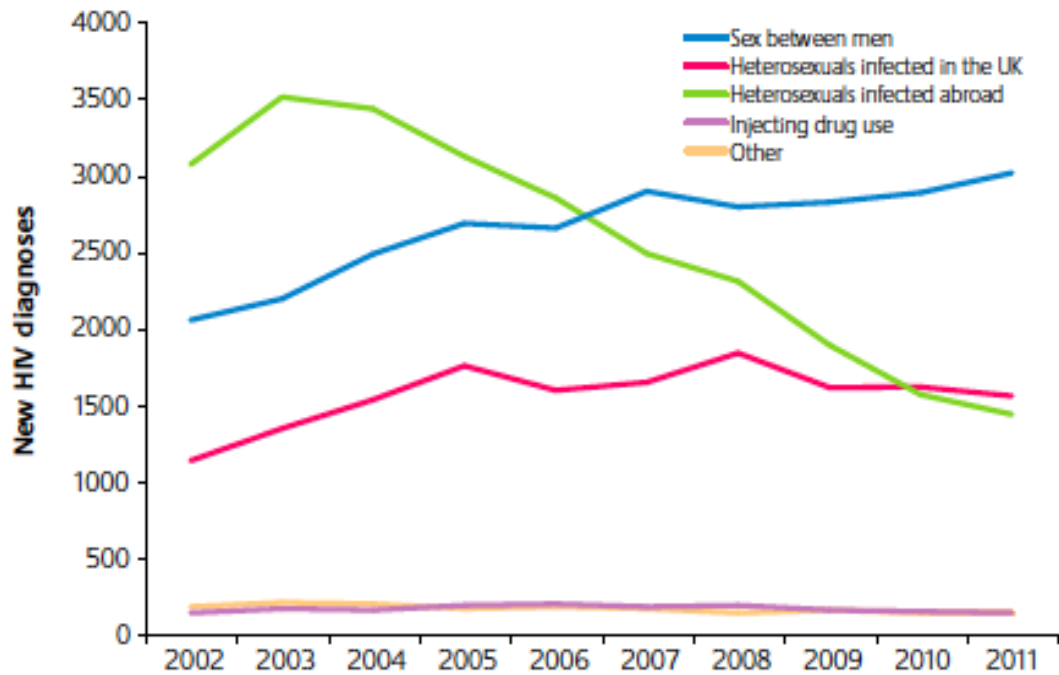
New diagnoses include both incident and long-standing infections. A back-calculation estimate suggests that HIV incidence and numbers of undiagnosed infections acquired by MSM in the UK has remained relatively constant over the past few years, despite an expansion in HIV testing in this population and a move towards earlier initiation of antiretroviral therapy(2).

Sixteen percent of MSM living with HIV are undiagnosed. This proportion is higher in male heterosexuals (34%) and female heterosexuals (29%) and is higher among black-African men (38%) and black-African women (31%) (table 1).

The large proportion of infections that remain undiagnosed means that almost half of HIV diagnoses are made at a late stage of infection (defined as CD4 count of fewer than 350 cells/mm3). Just under a quarter of new infections were diagnosed at a very late stage of infection with CD4 count fewer than 200 cells/mm3 in 2013.

However, once diagnosed, the treatment cascade for HIV in the UK suggests excellent retention in care for all groups. Almost all patients (97%) were linked into care within 3 months of diagnosis in 2013, which is consistent with British HIV Association guidelines(22). Over eighty percent (86%) were retained in care at 12 months after HIV diagnosis and 88% received antiretrovirals according to guidelines when CD4 count fell below 350. This picture appears to be consistent among ethnic and sexual groups and across regions in the UK.

Early HIV diagnosis is one of the cornerstones of HIV prevention. For the individual, early diagnosis empowers the individual to change sexual risk behaviour and allows treatment to be started early which is associated with improved health outcomes and reduced risk of onward transmission. Late HIV diagnosis is associated with reduced life expectancy and significant morbidity(23). Early HIV diagnosis is also associated with reduced costs to the health system; it is estimated that £63,061 is saved from one early HIV diagnosis(24).

Therefore, once diagnosed, and even more so once linked to care, the picture for those infected with HIV in the UK appears promising. However, a major gap lies in identifying those who are undiagnosed and preventing onwards transmission.

2.4 The HIV epidemic among men who have sex with men in the UK

Men who have sex with men (MSM) continue to a bear disproportionate burden of HIV infection in the United Kingdom. HIV diagnoses have continued to rise steeply since 1999, with the highest number of new HIV diagnoses (3,250) among MSM reported in 2013(1), equating to a diagnosis rate of 3.5 per 1000 (3.1-4.0) MSM in the UK(25). The number of new HIV diagnoses includes both incident and long-standing infections. HIV incidence is estimated to be stable at between 2300-2500 per year(2). An estimated 40,000 MSM are living with HIV infection in the UK, a prevalence of approximately 6%, of whom 16% remain undiagnosed(1). The majority of these men probably acquired their infection in the UK (76%)(1).

Data from the Recently Acquired Testing Algorithm (RITA) suggest a high level of ongoing HIV transmission among MSM(20). The proportion of recent infections (i.e. infected in the previous 4-6 months) among this population is 30%, higher than heterosexual men (13%) and women (13%). Estimates of HIV incidence suggest that most MSM living with undiagnosed HIV infection acquired their infection in the past three years. The sustained number of new infections entering the pool of undiagnosed infections suggests that HIV transmission is ongoing(1, 25, 26).

This is supported by a concomitant increase in reported high-risk behaviours such as non-concordant unprotected anal intercourse (UAI) with a main partner, in the London Gyms Survey among MSM between 1998 and 2008 respectively(27). A survey in 2008 of almost 7000 MSM reported more than half of MSM engaging in UAI(28). The resurgence in unsafe sexual practices is reflected in an epidemic of bacterial STIs(29). Since 2001, diagnoses of infectious syphilis and chlamydia have increased three-fold, and diagnoses of gonorrhoea have increased rapidly since 2008(25). People co-infected with HIV and other STIs are more likely to be infectious and to transmit HIV during sex(30). Almost one in five MSM who are newly diagnosed with HIV have an acute STI when diagnosed in a GUM clinic(1, 31) compared to 5.9% of newly

diagnosed heterosexual men and 2.8% of women. Some of this increase in unsafe sexual behaviour may be due to treatment optimism(27) and the use of social media that accelerates wider partnership formation(32, 33).

Over the past decade there has been a drive to strengthen prevention efforts, including guidance on HIV testing for at risk groups(34, 35) and behavioural interventions(36, 37). A 3.7 fold expansion in the number of HIV tests conducted in STI clinics among MSM in England and Wales between 2001 and 2010 has been mirrored by a reduced estimated mean time-to-diagnosis interval for MSM from 4·0 years (95% credible interval 3·8–4·2) in 2001 to 3·2 years (95% credible interval 2·6–3·8) by the end of 2010 using data from a back calculation model(2). However, despite this expansion in testing and prompt uptake of anti-retroviral treatment, HIV incidence among MSM has remained largely unchanged. By 2010, 80% of all diagnosed HIV infections were being treated with antiretrovirals, higher in those with a CD4 count of under 350 cells per μL. This suggests that current prevention strategies are inadequate(2).

It is possible that the expansion in HIV testing over the past decade has not improved the coverage of testing among MSM or the frequency of HIV testing among MSM, as reflected in the modest decrease in time-to-diagnosis over the same period(2). Recent cross-sectional surveys of 2409 MSM in Scotland and London suggest that only half (54.9%) of men test annually. Men reporting a higher number of tests tending to be younger, report higher numbers of partners, but not unprotected anal intercourse with two or more and/or unknown/discordant partners in the past 12 months(6). Swiss modelling studies suggest that rising HIV and STIs among MSM can be explained by risk behaviour rather than increased testing alone(38). This modest decrease in time-to-diagnosis may still be too long to capture primary infections, which are thought to be responsible for up to 50% of infections(39). Furthermore, estimates suggest that it is the undiagnosed infections, not untreated infections that represent the principal part of the community viral load reservoir that drives HIV transmission(40). Therefore, use of early treatment as prevention may not reduce HIV transmission unless the undiagnosed population is reduced also(41).

The current HIV testing strategy may therefore not be optimally targeting or reaching those MSM most at risk. Therefore not only do those MSM who remain undiagnosed need to be targeted, but it is also important to reach these men early in their infection when they have the highest viral load and have highest transmission potential. Several reviews have suggested that a strategy of regular and more frequent HIV testing for MSM should be considered(42-45). However, there is little interventional evidence to guide strategies and many research questions remain to guide implementation, including understanding what interventions provide an effective and cost effective way of increasing awareness and uptake of HIV testing among MSM(35). The experience of expansion in HIV testing has demonstrated that any new strategy needs to be both acceptable and feasible for its target population to ensure that those at highest risk engage with the intervention, and that HIV testing forms part of a broader prevention toolkit. Not only do we need to understand the optimal frequency for HIV testing, but we also need to understand why men would want to and be willing to increase the frequency of testing(46). Since there is high co-infection of HIV with acute STIs and infection with an acute STI increases risk of HIV transmission, recall for HIV testing and STI screening need to be considered together.

This thesis briefly discusses current HIV testing policy, the available evidence for recall reminders in sexual health, and a pilot intervention to actively recall MSM for HIV tests appropriate to sexual risk. It then outlines a mixed methods study that examines drivers and barriers to active recall for HIV testing for MSM and the policy implications of the findings.

In the next section, current testing guidelines for MSM in the UK are discussed, the uptake and suggested impact of these guidelines. The literature that argues that more frequent HIV testing is necessary and how this has influenced policy in other countries with a similar HIV epidemic is explored. The hypothesised benefits and risks of more frequent testing from the literature are examined, what the drivers and barriers to HIV testing can tell us and why an understanding of the drivers and barriers to active recall for HIV testing is important when developing a service strategy to actively recall MSM for HIV testing.

2.5 Current testing guidelines for MSM in the UK

The past decade has seen a drive to expand and normalise HIV testing(34). The evolution of the HIV epidemic in the UK over this period despite expansion in HIV testing and prevention activities has resulted in a targeted approach to HIV testing for MSM among other groups.

Current UK policy from the National Institute for Health and Care Excellence recommends 'at least annual' HIV testing for men who have sex with men. Public Health England reiterates this guidance, but adds that MSM having unprotected sex or sex with new or casual partners should have an HIV test every three months(20). Recent guidance from the British Association of Sexual Health and HIV (BASHH) and Public Health England recommends that MSM at high risk of STIs should be tested every three months, and this includes MSM reporting any unprotected sexual contact with a new partner, after diagnosis of a new STI or other markers of high risk such as drug use(1, 3). It encourages use of recall strategies for MSM diagnosed with an STI, e.g. using text message(3), but does not provide guidance for MSM who are not diagnosed with an STI. The Department of Health's sexual health framework recognises the need for increasing HIV testing for MSM to reduce undiagnosed and late HIV diagnoses(45).

Cross-sectional community surveys show that the targets of annual and three-monthly HIV testing are not being met. Over half of MSM test annually, 33.7% reported 2-3 tests in the last 2 years and 21.2% reported 4+ HIV tests in a survey of MSM in Scotland and England(6).

Early testing and diagnosis of HIV reduces treatment costs – £12,600 per annum per patient, compared with £23,442 with a later diagnosis(47). It is estimated that earlier diagnosis results in a cost per quality-adjusted life year (QALY) gain of £7,504(48).

2.6 HIV testing policy for MSM in other countries with a similar HIV epidemic

Similar guidance has been issued in other countries with high and increasing numbers of newly diagnosed HIV infection among MSM. In the USA, where the total number of new HIV infections in 2010 was 29,000, the Centers for Disease Control recommends 'at least annual' HIV testing(49). Three-monthly testing is recommended for people who are taking pre-exposure prophylaxis (PrEP) to reduce the risk of HIV infection and to detect seroconversion early to prevent antiretroviral drug resistance from developing(50). However, the National HIV Behavioural Surveillance System (NHBS) that sampled over 8000 MSM in 21 cities in the USA in 2008 found that adherence to annual HIV testing recommendations was low with only 61% having tested in the past year(51). Fewer than half (44%) of MSM reporting high-risk behaviours had been tested for HIV in the past 6 months. Of the HIV infected cases, 16% had never been tested for HIV and 29% had been tested during the past 6 months. Based on these findings, the CDC has suggested re-examination of current guidelines and consideration of HIV testing every 3-6 months for all sexually active MSM regardless of self-reported risk behaviours.

In Australia, HIV testing is recommended 'at least once a year' for all MSM who have had sex with another man in the previous year. More frequent testing three to six monthly is recommended for those men who have episodes of unprotected anal sex, have more than 10 partners in the past six months and who participate in group sex or use recreational drugs during sex(52). A study by Guy et al(53) of 2163 MSM found that retesting rates in primary care clinics were low: 35% (762/2163) of MSM who should have had an annual HIV test according to national guidelines did so and six-monthly HIV retesting rates were 15% (283/1862).

2.7 Regular versus repeat testing

Studies suggest that regular and repeat testers may be different groups of individuals. Regular testers, also described as maintenance testers (54), test

on a regular basis e.g. once a quarter, sometimes as part of a routine health check, and this may not be indicative of sexual risk(55-57). They have been described as having high internal control and are keen to have an early diagnosis and access treatment(54). They are less likely to have been diagnosed with an STI, perceive lower sexual risk, and report protected insertive anal sex(58).

Repeat testers, also described as risk-based testers(54), undergo additional HIV tests after receiving an initial negative result, often in response to a particular risk, change in relationship status or change in frequency of sexual behaviour(54, 56). Repeat testing among MSM has been associated with a history of STIs, higher number of sexual partners, having oral or unprotected insertive anal sex, and knowing someone with HIV infection(56, 58, 59).

Lee et al attribute routine testing to a 'health maintenance' approach, suggesting that individuals are responsible for their own health and take risks based on how they understand staying healthy(60).

Two further categories described in a study of testing patterns of 29 black MSM were convenience testers, who were influenced by cost and access to testing, and test avoiders who were influenced by fear of a positive result(54).

2.8 Evidence for more frequent HIV testing for MSM

Several studies have suggested that more frequent HIV testing for MSM at high risk of HIV infection should be considered(43, 44, 61). Estimates suggest that one in four to five MSM in the UK is diagnosed with HIV within six months of infection(20). Viral load is highest immediately after seroconversion(49), and the risk of transmission is highest at this point. More frequent testing may detect HIV in at-risk MSM when they are highly infectious. Studies show that most MSM diagnosed with HIV reduce their sexual risk behaviour after diagnosis(62-64); thus reducing the risk of onwards transmission. Data from the HPTN 052 study(65), START study(66, 67) and recent guidance from the British HIV Association(68) also suggest that MSM diagnosed with HIV could benefit from early treatment to reduce transmission potential. However, a

modelling study of ART coverage in the UK suggests that the benefit of treatment as prevention among MSM will be limited unless the HIV-undiagnosed population is also reduced through frequent HIV testing(40, 41).

A modelling study in the USA compared the cost effectiveness of annual versus three-six monthly HIV testing for MSM aged 14-64. They found that testing as frequently as three-monthly in this group was cost-saving when assessing HIV transmissions averted due to the patients earlier awareness of their serostatus(4).

A further recent modelling study by Gray et al in Australia suggested a 13.8% reduction in HIV infections over 10 years could be achieved by increasing the testing frequency of MSM who test at least once a year to four times per year(5).

A study in Scotland of 1350 MSM found lower proportions of HIV positive diagnoses among recent (within the last six months) testers(42). This could be attributed to the influence of health promotion and behavioural interventions received at the time of testing. However, it may also reflect a lower sexual risk profile of recent 'repeat' testers, suggesting that those at highest risk of HIV are not testing frequently.

Other risk reduction strategies, such as serosorting are supported by HIV status disclosure and frequent HIV testing forms the keystone of these strategies too(69). Although serosorting studies suggest that MSM who state that they are in monogamous relationships are at reduced risk of HIV infection(70), they may still have a risk of HIV infection if they practice UAI. A cross-sectional study of 2569 MSM in Israel demonstrated that 50% of respondents that had a steady partner also had a casual partner and almost a third practiced UAI with both partners(71).

A high proportion of MSM, 83%, who attend a GUM clinic have an HIV test(25) and 72% of MSM are offered at least one HIV test per year (HPA unpublished 2012). However, a recent retrospective audit of the notes of 598 MSM from 15 clinics in England found that a median of one HIV test per year was offered and accepted by MSM attending these clincs with no difference

between MSM who were at higher risk of HIV infection through UAI compared to those that were not(72). This suggests that those at highest risk of HIV infection are not being adequately targeted.

Not all MSM are offered or accept a HIV test at every STI clinic visit(25). Data from the sentinel unlinked anonymous HIV testing survey (GUMAnon) suggested that 32% of HIV infected MSM left a GUM clinic unaware of their HIV infection in 2009(25). However these data are limited by reporting bias by patients who may not disclose knowledge of their positive HIV status when attending a different clinic to the clinic used for their routine HIV care. In a cross-sectional on-line survey of 277 MSM diagnosed with HIV, 9.4% indicated that they had a STI screen at a service that was not their usual care provider and that they did not disclose their HIV status(73).

Clinics vary in their policy regarding recalling MSM at higher risk of HIV for a test. A cross sectional survey of GUM clinics in the UK found that only a quarter of clinics had a recall system in place for MSM who report a risk for HIV in the last three months(9). But we also know that men who are recalled do not always reattend. Half of MSM have never attended a GUM clinic, and so any clinic based recall system would not be able to target these men. Having never tested for STIs has been associated with high-risk UAI (UAI with two or more partners and/or UAI with casual partners and/or UAI with unknown/discordant partners in the past 12 months) in a community survey of 693 MSM in Scotland(74).

A further concern is that repeat testing for HIV has been associated with increased sexual risk behaviour among repeat or recent testers for HIV compared to first time testers(55, 75, 76); others have found no difference(55) or reduced sexual risk behaviour(77). New testing technologies such as 4th generation antigen/antibody tests can reduce the window period between infection and detection and detect acute HIV infection (though not in its very early stage), which is highly infectious.

2.9 Drivers and barriers to frequent HIV testing

There has been extensive work on the drivers and barriers to HIV testing(78-81), but fewer data exist to understand the drivers and barriers to frequent HIV testing. These drivers and barriers may be different for regular and repeat testing. Both drivers and barriers exist at the individual, clinic and structural levels.

A systematic review of qualitative evidence that looked at drivers and barriers for HIV testing(78) found that motivating factors include triggers such as higher risk sexual experiences(53, 60, 82-86), peer encouragement(85, 86), media campaigns (85)or advice from health service providers, the uncertainty of unknown HIV status(85, 87) and a sense of responsibility towards oneself or one's partner(84, 86). Preferences for testing services included community based, non-judgemental, gay-positive service providers and those that offer a high degree of confidentiality(78). Less intrusive methods of testing such as oral testing were preferred in several studies to blood testing(85, 86).

Several studies and systematic reviews have characterised barriers to HIV testing. These include inconvenience of location and availability of testing facilities(88, 89), denial(84, 87, 90-92), low perceived HIV risk(80, 81, 93, 94), mutual trust within relationships(60), anxiety associated with a positive test result(80, 84, 85, 87, 91, 92, 95-99) including loss of quality of life and worry about making changes to life-style(85, 86, 91), HIV stigma(80, 89, 100) and use of non-rapid HIV testing(101).

A barrier to regular HIV testing is being in a regular partnership. In a survey of 906 MSM recruited through the internet, partnered men in monogamous relationships had lower odds of testing for HIV in the past six months. They had higher odds of being confident that they would remain HIV-negative and higher odds of perceiving that they were not at risk of HIV compared to men in an open relationship(102). An analysis of testing patterns among MSM shows that men who had never been tested were less likely to be in an open relationship and had greater trust in their partner(103). Despite this, data from the National HIV Behavioural Surveillance System in the United States

suggests that most HIV transmissions among MSM are from main sex partners, highlighting the importance of targeting this group for increased testing frequency(104).

Predictors of frequent HIV testing were examined in a study by Guy et al. MSM who were classed as having higher sexual risk were more likely to test more frequently if they had higher numbers (11 or more) sexual partners in the past six months (adjusted OR 3.1, 95% CI 1.8-4.8, p<0.001) or reported a previous HIV test more than 12 months earlier (Adjusted OR 3.3, 95% CI1.9-5.5, p<0.001)(53). This may be due to more encouragement by clinicians to undergo regular testing.

A survey by Phillips et al(105) of MSM in the USA found that frequent HIV testers (those testing at least twice a year) were younger (adjusted OR 1.94 of being aged 18-34 compared to 35+) compared to annual or less frequent testers. Frequent testers were also more likely to know their last partner's HIV status (adjusted OR 1.86), have had at least five sexual partners in the past year (adjusted OR 1.52) or be engaged with health services (had seen a health-care provider in the past year) (adjusted OR 2.28) compared to annual or less frequent testers. However, frequent testers were less likely to be newly diagnosed with HIV infection (adjusted OR 0.27) or have had a main partner (compared to a casual partner) at last sex (adjusted OR 0.59) compared to annual or less frequent testers. The higher sexual risk may have motivated more frequent testing. Paradoxically, this greater engagement with health services and health promotion may have contributed to lower HIV diagnoses among frequent testers despite greater sexual risk compared to less frequent testers.

Studies have explored frequent HIV testing using different testing services, both clinic and home based(106). Self sampling using either direct blood spots or oral sampling has been demonstrated to be acceptable and feasible in the HIVNET cohort (HIV Network for Prevention Trials) and risk behaviours were reported to have stayed the same (77%) or become less risky (21%) in those undergoing twice monthly HIV testing. Self sampling is discussed in more depth in section 2.11.

Reasons for repeat HIV testing can provide some insight into drivers and barriers for frequent testing for HIV. A survey of over 2600 MSM repeat and regular testers in the USA found higher sexual risk (anal or oral sex, higher partner number, in serodiscordant partnership, unprotected sex) was associated with repeat and regular testing. However, this was not always appropriate as oral and not having anal sex were predictors of repeat testing(107). A survey in the UK of 1500 people having an HIV test found that repeat testing (previous HIV negative test) was associated with higher-risk unprotected sex among MSM (i.e. with a partner of positive or unknown HIV status, p=0.0002 and also with a history of STIs), and at the start of a new relationship(55). Other reasons for repeat testing have included recent risk and using the HIV test as a tool for self-care(108).

2.10 **Active recall**

Active recall is the use of a reminder to return for or to have a test or screen. This can take the form of a short message service (SMS), email, telephone call, letter, booking a repeat appointment for a patient, or sending out a self-sampling test kit.

Active recall has been extensively used in other healthcare settings, such as for immunisations. There have been several studies that have examined the effectiveness of active recall for healthcare appointments. A systematic review by Car et al found an improvement in reattendance rates at healthcare appointments with SMS reminders compared to no reminders (RR 1.10, 95% CI 1.03 to 1.17) and compared to postal reminders (RR 1.10, 95% CI 1.02 to 1.19). Phone reminders had a similar effect to text message reminders (RR 0.99, 95% CI 0.95 to 1.03)(109). They found however, that the cost of text messaging was lower (by between 55-65%) than phone reminders. User acceptability was high with 98% of patients in one study reporting that they were willing to receive text message reminders for their appointments(110).

A review of interventions to increase rates of re-screening for Chlamydia found evidence for mailing rescreening kits in increasing re-testing rates (RR 1.30, 95%CI 1.10 to 1.50) and for telephone reminders. However, they

reported little evidence for the effectiveness of text message reminders on re-testing rates(111).   Other studies have found text message reminders to have an impact on re-testing rates(112), and this evidence has been used by the UK Chlamydia Screening Programme(113). The data on active recall for improving reattendance for HIV and STIs are discussed in more detail in the systematic literature review in chapter 4.

Interactive SMS recall reminders, where participants can respond to the SMS or have a dialogue with the researcher, have demonstrated higher retention compared to SMS messages that do not allow interaction(114). Several reviews have demonstrated the positive impact of SMS on appointment attendance, adherence to medication and improving self-management(109, 115-117).

However, active recall reminders rely on recipients having engaged with services previously and can therefore be used to increase reattendance/re-testing rates.

2.11 **Self-sampling and home testing**

One form of active recall is to send out a test to the participant. For HIV, self-sampling is available in the UK. Home testing has been legalised since 2014; currently one kit is commercially available(118).

2.11.1 Self sampling

Self-sampling involves a patient taking his/her own sample, often oral fluid or a whole blood sample, and posting it back to a laboratory for analysis. Results are then communicated back to the individual. Often, an individual is encouraged to perform a risk assessment on-line before ordering the sampling kit and may receive or be directed to behavioural interventions. In the UK, self-sampling is available through several local and national internet sites.

HIV self-sampling can access those individuals for whom there are barriers to accessing a service(119) or who may not otherwise test(120). An evaluation by the Terrance Higgens Trust found that of the 9868 sampling kits distributed

over a nine month period in 2013, 73% of requests were from MSM, there was a 73% return rate and 1.8% positivity rate among MSM. Three quarters of those with a reactive HIV test accepted referral(121).   A retrospective cohort analysis of almost 175,000 self sampling kits distributed in their first year of availability in the USA found that 60% of all users and 49% of those who tested HIV positive had never been tested before(122). In comparison, 55% of people in the USA have never tested for HIV before(123), suggesting that self-sampling can access hard to reach groups. However, in a survey by Skolnik et al, only 1% (2/354) clients of a public testing service would choose self sampling as their first choice test, perhaps due to the poor timeliness of getting results. Accuracy/timeliness of results, privacy of test disclosure and linking of test results were considered to be the most important factors in making their choice(124).

2.11.2 Home testing

Home testing involves a person taking his/her own sample and performing a simple rapid laboratory test, which provides them with the result directly. Home testing is legal in the UK as of 2014(125). The Food and Drugs Administration in the USA approved an oral HIV test for home testing in 2012.

Advantages of home testing include confidentiality, convenience, earlier transition into treatment and care, facilitation of repeat testing, normalisation of HIV testing and reduced costs (as healthcare testing related costs are removed)(126-128).

Barriers to using self-testing include a concern that the tests have lower sensitivity and specificity compared to laboratory tests, psychological risk of knowing HIV status without appropriate counseling support, ensuring linkage to services for those with a reactive test, risks of unethical use of tests, concerns that self-testing might result in risk-compensation if the test result is negative and concerns around safe disposal of test kits(126-128).

Some of these concerns have been reduced. Oral testing can be highly specific but is less sensitive compared to blood based testing(129). It removes the sharps disposal hazard.

A study of risk intentions in Europe found that 62% of 1112 respondents said that they would avoid risk following self-testing and only 1% said that they would not avoid risk after self-testing(130). In the same study, 98% of respondents said that they would go to a doctor if they tested HIV positive on self-test. However, the study was industry led.

Studies suggest interest in self-testing. Cross sectional surveys of HIV negative/unknown status participants have shown high levels of acceptability for self-testing among heterosexual and MSM populations(131-134). A cross-sectional survey in the UK found that 91% of 18-35 year old men would be willing to self-test for HIV/STIs(135, 136).

Several research gaps remain in understanding the optimal use of self-testing. Napierala-Mavedzenge et al have identified that more research is needed to understand the effects of self-testing on uptake of first, repeat and recent testing. Further work is required to understand the effects of self-testing on sexual empowerment, HIV stigma, psychological effects where counselling is not provided and of a reactive test. An understanding of the acceptability of couples testing, entry and willingness to access onwards care, cost-effectiveness, quality assurance, marketing strategies, monitoring and evaluation is also needed(137).

2.12 **Drivers and barriers to active recall**

An understanding of the drivers and barriers to HIV testing and to frequent HIV testing gives us some idea of factors that might encourage or dissuade MSM from testing for HIV regularly. The effectiveness of active recall programmes may also indicate factors that are associated with successful programmes. However, this does not give us an indication of the drivers and barriers to active recall for HIV/STI testing. For a service to be acceptable and feasible, these factors also need to be explored.

2.13 **Conceptual framework**

2.13.1 Theory of Planned Behaviour

To help understand the drivers and barriers to reattending for a HIV/STI screen after active recall, this thesis uses a conceptual framework based on the Theory of Planned Behaviour (figure 4).

The Theory of Planned Behaviour, proposed by Ajzen[10] links beliefs and behaviours. It proposes that the individual's attitudes towards behaviours; subjective or social norms; and perceived behavioural control, shape an individual's behavioural intentions or motivation and their actual behaviour. This is true where 'perceived behavioural control' is an accurate reflection of 'actual behavioural control'. The relative importance of attitude, subjective norms and perceived behavioural control will vary across behaviours and situations.

DEFINITIONS IN THE THEORY OF PLANNED BEHAVIOUR(138)

Behavioural beliefs - the belief that a behaviour will result in a given outcome. The behavioural belief in combination with the value placed on the outcome determine the attitude to a behaviour.

Attitudes towards behaviours - the way that people evaluate the proposed behaviour e.g. if it is positively or negatively valued

Normative beliefs - expectations of important individuals regarding the behaviour e.g. spouse, family, friends. Together with a person's motivation to comply with these individuals, this determines the subjective norms.

Subjective norms - perceived social pressure to engage or not engage in a behaviour

Control beliefs - a person's perception of factors that can facilitate or hinder a behaviour. These can be external or internal factors. Examples of external factors may include clinic opening times, examples of internal factors may include confidence.

Perceived behavioural control - people's perceptions of their ability to perform a given behaviour(139). This is determined by the relative power of different control beliefs.

Intention - a person's readiness to perform a given behaviour. Note that non-motivational factors (e.g. availablilty of resources and opportunities) will act with intention/motivation to determine actual behavioural control.

Actual behavioural control - 'the extent to which a person has the skills, resources, and other prerequisites to perform a given behaviour'(140)

Behaviour - the observable response in a given situation to a given stimulus

The Theory of Planned Behaviour built upon the Theory of Reasoned Action, also proposed by Ajzen with Fishbein(141). This theory proposed that a person's attitudes towards behaviour and subjective norms determine the person's intentions or motivations to carry out the behaviour, and as a result they are more likely to carry out that behaviour. Studies have shown a high level of correlation between attitudes and subjective norms with behavioural intention and subsequent behaviour(142).

However, the Theory of Reasoned Action did not explain why behavioural intention does not always lead to actual behaviour and was only able to predict volitional behaviours. Ajzen, in his Theory of Planned Behaviour, suggested that 'perceived behavioural control' played an important role in determining which behaviours were ultimately carried out.

The concept of 'perceived behavioural control' comes from Bandura's idea of self-efficacy(143). This is the belief in one's ability to succeed in specific situations. Bandura's studies suggested that people's behaviour is strongly influenced by their confidence in their ability to perform it. In turn, self-efficacy will influence the effort put into a behaviour succeeding(144). Where a person has complete control over their behaviour, intention alone should be able to predict actual behaviour. However, as a person's control over the behaviour reduces, perceived behavioural control becomes increasingly important.

Conceptually, Azjen argues that there is no difference between perceived behavioural control and self-efficacy. They both refer to people's beliefs that they are capable of performing a given behaviour. However, in practice, the two concepts are often assessed in different ways. In assessing self-efficacy, participants are usually asked how likely they are to overcome given obstacles, whereas in assessing perceived behavioural control, participants are asked to rate how much the behaviour is under their control(145).

However, perceived behavioural control is widely seen as an overarching construct with distinct but inter-related subcomponents: controllability and self-efficacy(146). Controllability reflects 'perceived controllability' (how much control the participant feels they have over the behaviour) and 'perceived locus of control' (where the participant feels that performing the behaviour is

up to him/her). Self-efficacy reflects how difficult a person perceives the behaviour will be to carry out and their confidence in being able to carry it out(147).

The Theory of Planned Behaviour has been shown to predict health related behavioural intention better than the Theory of Reasoned Action(148, 149) and has been used widely in understanding condom use(150), exercise(151, 152), and diet(152-155). Meta-analytic reviews suggest that the Theory of Planned Behaviour can account for 41% of the variance in intentions and 34% of the variance in behaviours(156).

However, it has been criticised for not accounting for the influence of emotions on health related behaviours(157) and for predicting self-reported behaviours better than observed behaviours. However it is still capable of explaining a large proportion in the variance of observed behaviours)(158-160).

Figure 4: Theory of Planned Behaviour (taken from Ajzen 2006)(138)
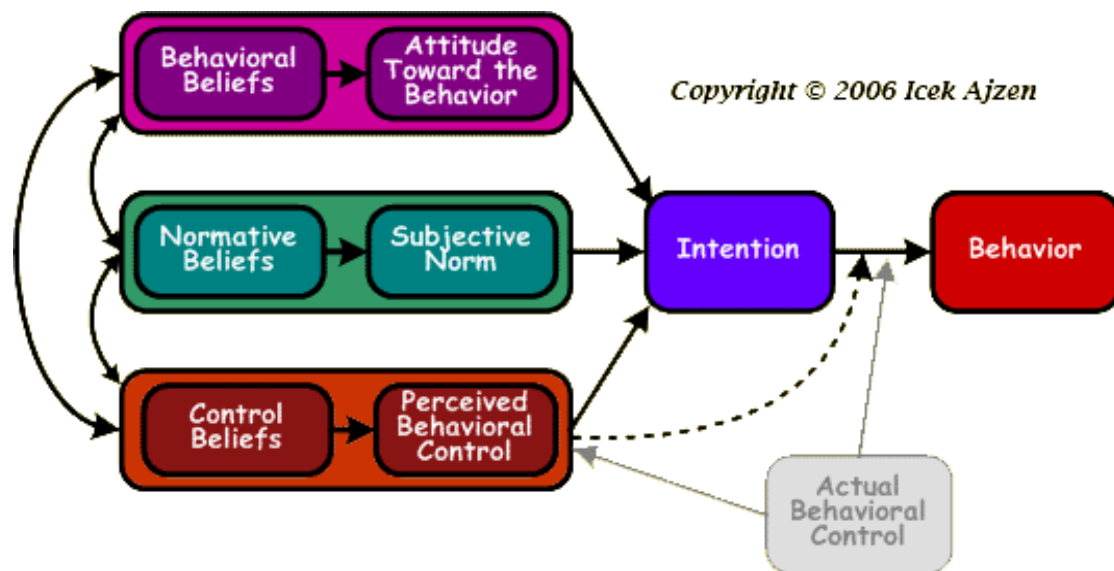
Although they have been used in studies of behaviour change in HIV, other behaviour change models, such as the Health Belief Model and Stages of Change Model are not used in this thesis for several reasons(161). The Health Belief Model is a cognitive model that suggests a person has to feel threatened by a health threat and feel that the consequences are severe

enough to change a behaviour(162). A person has to have self-efficacy (the ability to adopt the behaviour) and cues to action that trigger the actual adoption of a behaviour. However, inter-relationships between the components of the model are not well defined and it does not include broader contextual factors such as social and economic determinants of health that influence behaviour(163).

The Trans-Theoretical model (TTM) which encompasses the Stages of Change Model is a biopsychosocial model that proposes that people move through a series of changes to modify behaviour, such as precontemplation, contemplation, preparation, action and maintenance. Maintenance requires a sense of self-efficacy to maintain the desired behaviour change, decision-making ability to weigh up the pros and cons of the problem behaviour and certain processes of change, such as self and social liberation(164). The TTM model has been more commonly used in interventional programmes for changing health behaviours rather than only identifying correlates of relationships. However, there are concerns that it does not include broader contextual social and economic factors(163). In addition, the evidence that the TTM model predicts behaviour is limited(165). Furthermore, this study aimed to understand what factors were associated with intention to perform a behaviour and performing the behaviour, rather than changing behaviour per se.

2.13.2 Conceptual model

Using evidence from other studies of active recall and the evidence discussed earlier about drivers and barriers to frequent HIV/STI testing, the Theory of Planned Behaviour(166) can be modified to present a conceptual model for active recall for HIV/STI testing.

A systematic review that looked at mobile phone messaging reminders, a form of active recall, for attendance at healthcare appointments found that barriers to active recall included social barriers, such as concerns around confidentiality, concerns about impact on health inequalities. Barriers to perceived behavioural control included concerns about lack of understanding or misinterpretation of messages and problems with literacy. Barriers at a

structural level included costs for back-up systems, opportunity costs of time to send a text message.

Therefore, using these findings and the understanding of drivers and barriers to HIV testing, the Theory of Planned Behaviour(166) can be modified. In the case of active recall for repeat HIV/STI testing behavioural attitudes might include the perception of one's own risk which might be influenced by biological variables such as symptoms of HIV/STIs (figure 5). Attitudes will be influenced and interact with social norms around both testing and active recall. These will also interact with perceived behavioural control over reattendance when actively recalled. Together these factors will determine a person's intention or motivation to reattend if recalled. This will be influenced by non-motivational factors too, such as clinic factors, like opening times and ease of getting results and structural factors, such as cost of testing will influence this.

Active recall could empower an individual to take control of their sexual health and change their testing behaviour, changing their probability of reattendance for HIV/STI testing/retesting.

Structural factors have been shown to facilitate reattendance in recall strategies for sexually transmitted infection and include use of active recall(167) such as text messaging(112, 168, 169), telephone reminders(170, 171) and automatic delivery of home test kits(172).

Reattendance can have biological, behavioural and social outcomes. Biological outcomes may include changes in the timeliness of diagnosis of HIV and STI infections, changes in timeliness of treatment of HIV and STI infections and consequent changes in transmission rates of HIV and STIs. Behavioural outcomes may include changes in sexual risk behaviour, changes in testing frequency and changes in population demographics of those testing. Social outcomes may include changes in social norms around testing and impact on cost-effectiveness of testing.

Figure 5: Conceptual framework of active recall and behaviour change
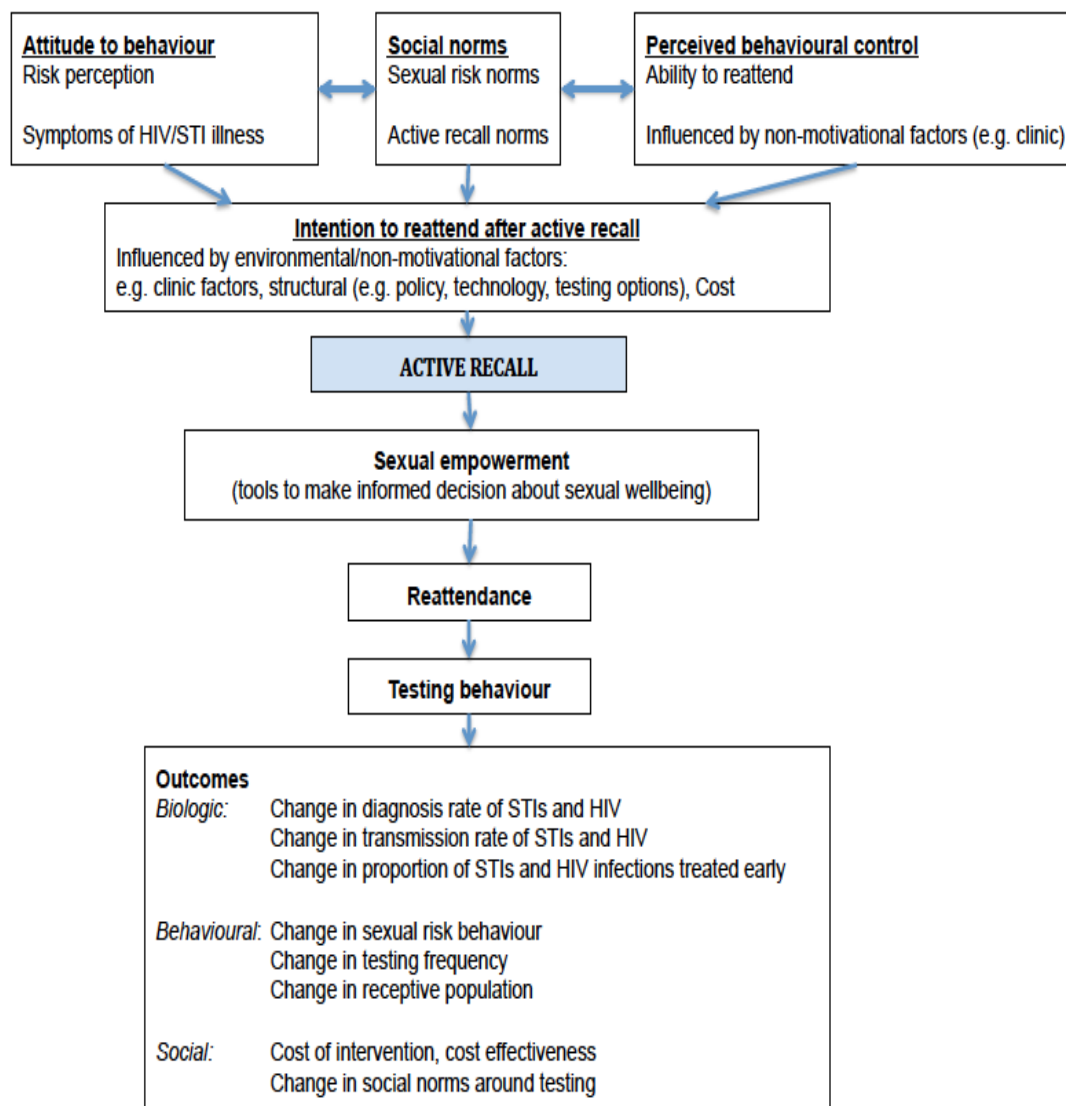
2.13.3 Measurements in the Theory of Planned Behaviour

There are several conditions that need to be met to accurately predict actual behaviour. Firstly, measures of intention and perceived behavioural control need to be compatible with the actual behaviour(173). For example, if the behaviour that we are trying to predict is 'retesting for HIV/STIs', we need to assess intentions to 'retest for HIV/STIs', not just intentions to retest in general.

Secondly, intentions and perceived behavioural control need to remain stable without influence from intervening events.

Thirdly, perceived behavioural control should accurately reflect actual behavioural control.

In designing any questionnaire based on the Theory of Planned Behaviour, Ajzen advises the following construct(147):

1. Define the behaviour in terms of target, action, context and time
2. Specify the research population
3. Formulate items to assess each of the theory's major constructs:
    a. attitudes
    b. perceived norms
    c. perceived behavioural control
    d. intention

This approach underpins the development of the questionnaire survey that is discussed in chapter 6.

2.14 Programme Science

This thesis study uses the principles of programme science to guide evaluation of the service development in chapter 5.

Programme science is the "application of theoretical and empirical scientific knowledge to improve the design, implementation and evaluation of public health programmes"(174). By understanding the epidemiology of a health problem including the relative importance of sub-populations, prevention efforts can be prioritised. This data can be used in modelling studies along with evidence of effectiveness of interventions to predict which mix of interventions is likely to be most effective in this particular context.

These evidence-based predictions are used to design interventions. When designing an intervention programme, resource allocation, prioritisation of populations and intervention packages and boundaries for the programme in the context of the wider environment are all considered.

Programme science recognises that context is complex, fluid and heterogenous as it includes social, cultural and political factors. As a result,

the programme science approach facilitates the choice of the most appropriate strategy for the population, the time and the scale and efficiency required and aims to have maximal population impact.

Outcomes and impact evaluations are needed. Process evaluation is an important component of programme science to understand the causal mechanisms by which given interventions work for specific groups in specific settings(175).

However, the process is iterative. The evaluation of an intervention results in new research questions being formulated. New knowledge can then be used to aid design and implementation of future programmes.

Therefore, the key components of programme science are:

1. Strategic planning- facilitated by understanding the problem at both high and local levels
2. Programme implementation- needs an understanding of the evidence for different interventions and tailoring interventions to local settings
3. Programme management- scaling up, monitoring and impact evaluation are important

The programme science framework has begun to be used through The Global Programme Science Initiative, set up by the Center for Global Public Health in six countries, including India, Pakistan, Nigeria and Kenya to target HIV prevention.

Sexual behaviour is dynamic and as a result, achieving sustained risk reduction is challenging. The programme science framework lends itself to sexual health prevention interventions, in particular where the epidemic is dynamic, where evidence for effectiveness of interventions is complex and where contextual factors are important and changing.

Observational studies, such as those conducted in this programme of studies, are well placed in Programme Science research as they allow assessment of the intervention at the practice level. Such studies can be used to assess drivers and barriers to the intervention. Although observational studies and

evaluation design studies can provide practically useful evidence to guide programme implementation, they are unable to provide the rigorous assessment of effectiveness provided by well conducted randomised controlled trials(176).

2.15 **Gaps in the literature and contribution of this thesis**

This background chapter has highlighted several gaps in the existing literature about active recall for HIV and STI testing. Firstly, there has been no systematic review of the evidence for active recall for HIV and STI testing. The review in chapter 4 provides the first systematic literature review and meta-analysis of active recall for HIV and STI testing, and the service evaluation in chapter 5 adds to the evidence base.

Despite use of active recall to remind patients to test for HIV and STIs and national guidance recommending use of text message reminders to recall MSM diagnosed with an STI(3), there has been little longitudinal assessment of the factors associated with intention or actual reattendance on receipt of a reminder to test for HIV/STIs among MSM. Although some studies have explored reminder preference(177), no study has attempted to use a theoretical framework to understand the reasons for and contextual drivers for reattendance on receipt of reminders among MSM. The survey questionnaire and in-depth interviews explore these issues in a mixed-methods study approach.

2.16 **Conclusion**

This background chapter has highlighted the problem of undiagnosed and late diagnoses of HIV infection. It has discussed that an increase in HIV testing coverage has not abated the epidemic among MSM in England. An increase in testing frequency can contribute to diagnosing HIV infections earlier; there are several ways in which to increase testing frequency including active recall. However, any service development using active recall to increase HIV/STI retesting rates needs to understand the drivers and barriers to retesting when receiving a reminder to test for HIV/STIs.

Therefore, this thesis explores what the drivers and barriers are to active recall for HIV/STI testing among MSM. It begins by exploring the current literature on active recall for HIV/STIs to understand whether this is an effective intervention in increasing retesting rates. It then assesses a service development and evaluation of active recall using a text message reminder in a large sexual health clinic. Finally, using a mixed methods approach underpinned by the Theory of Planned Behaviour, it explores the drivers and barriers to active recall for retesting/re-attendance for HIV/STIs to suggest policy, practice and research implications.

The next chapter outlines the overarching research question, study objectives, study methodologies used and their limitations.

Chapter 3   Research question, aims and objectives and methodology

3.1 Introduction

The previous chapter provided the contextual background for the thesis. It placed the HIV epidemic among MSM in England within the context of the global and national HIV epidemics. It discussed the rationale for frequent HIV testing, how the use of active recall reminders could increase testing rates among MSM and the conceptual framework that might underpin the mechanism by which MSM reattend/re-test if they receive an active recall reminder to test.

The thesis addresses one overarching research question that is outlined in this chapter. The programme of work comprises a number of linked study components using a range of methodologies: systematic review of the literature, service evaluation, survey questionnaire, cognitive interviewing and in-depth interviews. The questionnaire development included a cognitive interview step.

This chapter provides an overview of the methodologies used, their limitations, and how these could be overcome.

3.2 Research question

This research addressed the question: what are the drivers and barriers to active recall for HIV and STI testing among men who have sex with men (MSM) of negative or unknown HIV status?'

3.3 Definitions

Active recall: reminder to return for or to have a test or screen. This can take the form of a short message service (SMS), email, telephone call, letter, booking a reattendance appointment for a patient, or sending out a test. It does not include a verbal reminder at the initial visit.

Driver: a factor that encourages or facilitates a person carrying out an action, either consciously or not.

Barrier: a factor that dissuades or prevents a person from carrying out an action, either consciously or not.

3.4 **Objectives**

The objectives of each of the components of the programme of work were:

- Systematic review of the literature: to determine whether the published literature provides evidence for the effectiveness of active recall

- Service evaluation: to assess whether an active recall intervention for HIV negative/unknown HIV status MSM using SMS reminders increases reattendance rates

- Questionnaire survey: to determine the intention of HIV-negative/unknown HIV status MSM to reattend/re-test for HIV/STIs if they were to receive an active recall reminder, reminder preference and the facilitators and barriers to engagement with active recall for HIV/STIs

- In-depth interviews: to determine what are the drivers and barriers to HIV testing, testing frequency and active recall reminders; how and why they influence intention to reattend, and what are the contextual factors that influence these drivers and barriers

The programme of work focuses on HIV-negative/unknown HIV status MSM since this is a population with subsets at higher risk of HIV and STI infection who do not regularly engage with sexual health services. The programme of work does not focus on MSM diagnosed with HIV. Ninety-five percent of MSM diagnosed with HIV infection are engaged with sexual health services in England(1) and regular sexual health screens form part of best practice guidelines for MSM diagnosed with HIV. The drivers and barriers to active recall for STI screening are likely to be different for MSM diagnosed with HIV compared to HIV-negative/unknown status MSM.

3.5 **Methodology**

This section provides an overview of the methodologies used in each part of the research programme, the reasons for choosing the methodology and how any methodological limitations were addressed. The main methods used in the thesis are systematic literature review, service evaluation, survey methods, cognitive interviewing, and in-depth interviews. Detailed methods are presented in each study chapter. The systematic literature review is not discussed in this chapter, but is presented in chapter 4. The service evaluation is discussed in chapter 5.

The mixed methods study aimed to explore the intention of MSM to reattend/re-test for HIV/STIs if they were to receive an active recall reminder, reminder preference and the facilitators and barriers to engagement with active recall for HIV/STIs by MSM. Using a mixed methods approach, the questionnaire survey was used to quantify the factors associated with intended and actual reattendance for HIV/STI testing and the preferred options for reminders. Cognitive interviewing was used to refine the design of the survey tool. Qualitative methods were used to understand *how* reminders for HIV/STI testing influence reattendance and what the contextual factors are that influence these decisions.

3.5.1 **Questionnaire survey**

A cross-sectional survey of MSM attending the Mortimer Market Clinic was conducted using a survey tool that covered four topic areas:

1. Demographics
2. Sexual health: HIV and STI testing history, STI infection history
3. Sexual risk behaviour
4. Attitudes to active recall for HIV and STI testing
   a. Preferred frequency of HIV and STI testing recall
   b. Preferred place of HIV and STI testing
   c. Reminder preference for HIV and STI testing

The questions in the survey were informed by the Theory of Planned Behaviour (see chapter 2). The components of the Theory of Planned

Behaviour included behavioural attitudes, subjective norms, perceived behavioural control and behavioural intention of reattendance. Documented behaviour was elicited by capturing reattendance data from clinical records. As far as possible, questions were designed using the construct recommended by Ajzen(147), and taken from validated surveys on sexual health (appendix 4.4). Where no validated questions were available, questions were based on published evidence.

The survey was pretested using expert review and cognitive interview.

The next section outlines the cognitive interview and survey design methodologies that were used to develop the questionnaire, and their limitations.

3.5.1.1 Cognitive interviews

Cognitive interviews were used to identify problems in the survey tool, predict what might happen in the field, and inform the design of questions with the aim of improving the quality of the survey. The principal cognitive interview technique used was 'think aloud', which encourages the respondent to talk out loud about how they perceive the question being asked and allows the interviewer to determine whether the question interpretation matches the objective for that question.

3.5.1.1.1 Theory of cognitive interviewing

Cognitive interviewing is a form of in-depth interviewing that was developed in the 1980s in a collaboration between survey methodologists and psychologists. An example of this collaboration was the 1983-4 Advanced Research Seminar on Cognitive Aspects of Survey Methodology (CASM)(178). Since then, this technique has been used widely in the USA and more recently in Europe and the UK.

Cognitive interviewing focuses on the respondent's thought process when answering a survey question, in contrast to in-depth interviews which focus on the respondent's actual attitudes and behaviours. By focusing on the cognitive process that respondents use when answering survey questions, cognitive interviewing allows both covert (e.g. what the respondent is thinking)

and observable processes (e.g. body language) to be studied. It aims to understand how the respondent goes about determining his/her answer, what difficulties or ambiguities there are for the respondent when attempting to answer the survey question and how the respondent tries to handle these difficulties.

The mental processes assessed during cognitive interviewing have been outlined by Tourangeau(179, 180) and include comprehension, recall, judgement and response.

Comprehension refers to the understanding of the question. Specifically, it seeks to understand what the respondent believes the question to be asking (question intent) and what the specific words and phrases in the question mean to the respondent (meaning of terms).

Recall refers to the respondent retrieving relevant information from memory, in particular what types of information the respondent needs to recall to answer the question (recallability of information). Examples include the time period that the respondent refers to. It also includes the types of strategies the respondent uses to retrieve information (recall strategy). For example does the respondent estimate their response to a numerical question or calculate an accurate answer? As frequency of an event increases, people rely on estimation more(181). This is particularly relevant to this study, as it asks participants to recall the number of sexual partners they have had in a time period. If we ask too long a time period, we risk participants estimating, rather than calculating their answer, and too short a period may not present a true reflection of their sexual risk.

Judgment encompasses the judgmental heuristics that are used. For example, is the answer easily available to the participant? How representative is the answer of what the respondent usually does? Does the respondent 'anchor and adjust'- i.e. does the respondent adjust his/her answer based on an easily accessible response? For example, if a person is asked how long ago they last had casual sex, they may refer back to a notable event (for example, a birthday) and guess that casual sex may have occurred at a party the weekend after that event. Judgment also assesses

social desirability that may affect the answer and the motivation of the respondent to answer the question.

Response process seeks to understand whether the respondent can match his/her response to the response categories offered by the survey.

The cognitive interview process attempts to find clues to understand these processes.

However, there are several limitations to the cognitive interview process. Firstly, only a small number of respondents are sampled, meaning that the results may not be generalisable to the general population. Secondly, if the questionnaire has several routes due to skipped questions, some of the less common routes may not be adequately tested. Therefore, the selection matrix for sampling for cognitive interviews is important. Finally, both implementation and analysis techniques vary widely(182).

3.5.1.1.2 Cognitive interview techniques

There are two main types of cognitive interview techniques: think-aloud interviewing and verbal probing. Observation is also utilised. This discussion focuses on think-aloud, as this is the principal technique used in the study. Verbal probing techniques were used to supplement think-aloud, and are briefly discussed.

Other techniques that can be used include paraphrasing, use of rating tasks, response latency and free-sort and dimensional-sort classification tasks. The section on alternative methodologies touches upon these.

<u>Think-aloud</u>

"In a true think-aloud interview, the subject verbalises his or her thoughts while engaged in a cognitive activity, with little interjection by the interviewer" (183)

'Think-aloud', previously called 'protocol analysis' was the main technique used in this study. The 'think aloud' technique was developed from experimental psychology and pioneered by Simon and Ericsson in 1984(184). In this technique, respondents are asked to 'think aloud' as they answer a

survey question. The respondent needs to be trained in the technique before the interview begins.

An advantage of the 'think-aloud' technique is that it is relatively free from interviewer bias as the interviewer does not contribute to the interview other than occasional prompts to encourage 'think-aloud'. It should also have an open-ended format allowing the respondent to speak freely. As responses are collected concurrently, responses may be more reflective of the true thought process(185).

'Think aloud' relies on the participant being able to accurately report their thought process. It assumes that reporting their thought process does not change the activity they are reporting about(184).

However, 'think-aloud' has several disadvantages and may not be universally appropriate. The respondent needs to be trained in the technique, which takes time and may encounter resistance from the respondent. The respondent can stray from the task, which requires interviewer interjection. The process of 'thinking aloud' may result in respondent bias as more cognitive effort is required than just answering the question. The respondent may use different cognitive processes than he would do in real life in the knowledge that an interviewer is present and may be able to clarify some questions. Interjections by the interviewer, even so much as a nod or 'okay', may have an effect on the nature of the interview and results(186). Social desirability bias may also affect responses, in particular in the presence of an interviewer(186, 187).

In this study, the 'think-aloud' technique was used in preference to other techniques in order to minimise interviewer bias and to understand the true thought process underlying responses to questions. This enabled the interviewer to explore whether the questions measured what they set out to measure (construct validity of the survey).

Verbal probing

Verbal probing, which emerged out of respondent debriefing(188), was used to complement 'think-aloud' techniques in this study. Verbal probing

developed out of traditional survey methodology(188, 189). In this study, verbal probing was used after a 'think aloud' response was given to elicit more specific information about the question being tested. Probes were used to explore the respondents' thought process in more detail. Both pre-prepared and spontaneous probes were used. Categories included comprehension, paraphrasing, recall, confidence, specific probes and general probes. Examples included phrases such as "What does the term xxx mean to you?" which is a comprehension probe.

Use of verbal probes allowed the interviewer to control the path of the interview and avoid irrelevant discussions. It requires little training compared to "think aloud".

However, use of verbal probes has been criticised for creating an artificial environment in which the respondent is not able to express him/herself openly. It also risks creating respondent bias if leading probes are used. To reduce this bias, retrospective probing can be utilised in which the probe is administered at the end of a section of the survey or end of the whole survey. This is particularly of use in self-completion questionnaires to see how easy the respondent finds navigating the survey tool, and was used in this study.

3.5.1.1.3 Current issues in cognitive interviewing

The aim of cognitive interviewing is to identify problems in the survey tool, predict what will happen in the field, and inform redesign of questions, with the aim of improving the quality of the survey. There is good evidence to suggest that, when conducted properly, cognitive interviewing is able to do this(190-192). This enhances the construct validity (the extent to which the survey tool measures what it claims to) of the survey. It can also enhance reliability by refining ambiguous terms(193). However, Willis notes that cognitive interviewing does not formally test validity, but rather provides information to enable questions to be improved(186).

However, it has been widely recognised that there is much heterogeneity in the objectives and procedures used in cognitive interviewing(194-196). An experiment that compared different implementation techniques (e.g. using field interviewers compared to professional researchers) in cognitive

interviewing found differences in results and in methodology used(182). As a result, there is a call for standardisation of cognitive interview techniques, some calling for predominantly 'think aloud'(185), some for predominantly probes(197) and some for a balance of both(198).

3.5.1.1.4 Alternative methodologies

There are several alternatives to think-aloud and verbal probing that can be used to test survey questions using participants. Paraphrasing asks the respondent to rephrase the question in their own words and can be useful to clarify assumptions. This technique was occasionally used in this study to clarify study instructions. However, a weakness of this method is that the participant may feel embarrassed if they can't articulate or don't understand what the question is asking.

Rating tasks ask the respondent to rate items related to the question along a specified dimension. For example, we may ask the respondent to rate how sensitive the question is or how difficult the information is to recall. This approach can be subject to respondent bias as people may not want to admit to finding a question difficult or sensitive.

Response latency measures how long it takes from the time a question is presented to a response being given. It is unobtrusive, but may not be meaningful as latency may not be associated with difficulty in answering a question.

Free-sort and dimensional-sort classification asks participants to group concepts together and may help to confirm categories used by a survey. However, it is less useful for areas of the survey where there are no groupings.

Observational methodologies include behaviour coding, in which overt cues are noted, such as the need to repeat a question or the respondent asking for clarification. This method uses predefined codes, and is therefore regarded as a systematic and objective means of evaluating survey questions(199).

Other methodologies that test construct validity that do not use participants include expert review. Experts are asked to critically appraise a questionnaire

survey. Expert review can consist of individual or group review and informal or formal appraisal using an appraisal system such as the Forms Appraisal System(200).

Studies comparing the techniques have found that despite the small sample size, cognitive interviewing is effective in identifying problems with question comprehension. Behaviour coding detects problems that the interviewer was not able to pick up on and expert review identified most problems in surveys(196, 201). Willis et al also found a moderate degree of consistency between the different techniques(196).

3.5.1.1.5 Analysis of cognitive interview data

There is a lack of consensus and guidelines on the optimal method of analysing cognitive interview data(193, 202, 203). Materials usually available for analysis include audio recordings, completed test questionnaires, interviewers written notes (usually completed after the interview) and interviewer debriefing sessions.

Transcription and systematic qualitative analysis of audio-recorded cognitive interviews has been widely used in the Netherlands. An advantage of this method is that rigorous content analysis can be performed and particular kinds of question problems can be identified(203). However, if the purpose of the cognitive interview is a practical one- to modify the survey tool, this method has been criticised for being time-consuming and a more practical approach is to use interviewer notes(186, 204).

Willis(186, 197) recommends the use of more informal analysis. He recommends use of field interviewer notes made immediately after each cognitive interview and uses a blank questionnaire as a tool on which to record interviewer notes across all respondents. These notes can then be used in conjunction with the audio recordings to generate key messages for each part of the questionnaire. In this method, the audio recordings do not necessarily need to be transcribed and formally analysed.

There is however debate on how much importance should be placed on interviewer notes compared to subject's responses. Conrad and Blair argue

that respondents' responses should be relied on more heavily as they are closer to the level of the observed data(205).

Taking a practical approach that allows for a balance between completeness and timeliness, Willis suggests not using standardised analysis of transcribed interviews, but instead using a mixture of direct quotes from each respondent and interviewer notes from each interview for each question in the survey. Categorising the notes by question allows for common themes and hence recommendations to be drawn for each question in the survey. The annotated questionnaire that aggregates all the comments for each question can be used as a final report(186).

Several groups have developed coding frames that are loosely or more closely based on the cognitive model of comprehension, recall, sensitivity and response category(196, 201). The vast majority of data tend to sit within the comprehension category(206).

At the National Centre for Social Research, a similar approach to that advocated by Willis is used. It uses a grid based coding frame based on Framework Charting(207). Framework Charting is a tool to support data management, which includes data sorting and indexing and also data summary and display. The framework used can be generated using a top-down approach based on theoretical frameworks or a bottom up approach. Each theme, subdivided into sub-themes is used to form a matrix in which each participant is allocated a row and each sub-theme a column. In cognitive interviews, the cognitive themes include comprehension, recall, judgement and response. This allows for triangulation of data from completed test questionnaires, interviewers written notes, review of audio recordings and interviewer debriefing notes. Both within-case and across-case comparisons can be made. This is the approach used in this thesis, as it allows for cross-thematic comparisons to be made.

Analysis can occur at the question-response stage, which corresponds to the individual description of the question (in-interview analysis), by patterns of response (i.e. what the question captures- across interview analysis) and by

subgroups to understand if there is potential for bias (across sub-group analysis).

The outcomes of the analysis that help to improve the survey can include item-specific recommendations to improve cognition, structure or to make the question more culturally appropriate. There may be a recommendation to change or improve objectives and how they relate to the questions or to change the ordering or interactions between survey questions. A broader outcome may be in relation to the layout or length of the survey tool(186).

A major limitation in drawing conclusions from cognitive interviews is the small sample size. As a result, analysis may not occur to saturation and responses risk not being generalisable to the source population. To minimise this bias, participant characteristics can be compared to the source population.

Ideally, the cognitive interviewing process should be iterative with different versions of the survey tool tested in sequential rounds of interviewing, followed by a field test of the final survey(204). In this study, only one round of cognitive interviewing was performed due to financial constraints.

3.5.1.2 Surveys

The questionnaire survey was used to determine the factors and attitudes associated with intention to reattend/re-test for HIV/STIs. The survey sampled purposively, was delivered in a sexual health clinic and asked questions about sensitive topics in sexual health. As a result there were several methodological considerations particular to sexual health surveys that were considered in planning the survey, which are outlined below.

3.5.1.2.1 Validity and reliability

A questionnaire survey should be assessed to see if it meets the required standard of validity and reliability(208).

Validity refers to the extent to which the measurement process measures what we intended it to measure(209). Using the Theory of Planned Behaviour as a conceptual model for the survey, this survey was intended to measure the behavioural intention of the respondent to reattend if actively recalled.

Validity has several components. Construct/theoretical validity refers to the extent to which the measurement tool measures what it claims to. For example, in the survey in this thesis, does the survey measure intention to reattend? Cognitive interviewing assessed some aspects of construct validity.

Construct validity can be further subdivided into criterion, face and content validity.

Criterion validity (i.e. how well the measure predicts future outcome) can be subdivided into concurrent (i.e. measure of a simultaneously occurring event) or predictive (i.e. measure of a future event) validity. In this survey, predictive validity was measured by linking the survey responses to clinical data and assessing whether the respondent who intended to return for a repeat HIV/STI screen if actively recalled in fact reattended in three-five months time.

Face validity refers to a subjective judgement that the survey instrument is measuring what it is supposed to. In this survey, face validity was assessed by expert review.

Content validity refers to the extent to which the survey instrument measures all aspects of the social construct, in this case reattendance after active recall. In this survey, content validity was increased by using the Theory of Planned Behaviour as a conceptual model to ensure that all factors that might influence the behaviour are measured.

Reliability refers to the extent to which the measurement process provides consistent results. Internal reliabilty is a measure of the extent to which items in a multi-item scale are measuring the same thing. The survey instrument did use nor aim to develop a multi-item scale. However, Cronbach's alpha was used to test internal reliability(210) of groups of questions that aimed to measure the same construct (e.g. behavioural attitudes to testing). Cronbach's alpha tests the internal consistency or reliability of multi-item scales(211). It is a function of the average inter-item correlations and the number of items in the scale. The higher the Cronbach's score, the higher the reliability of the scale, with 0.7 being seen as an acceptable reliability coefficient(211).

There are several criticisms of Cronbach's alpha in the literature. Firstly, alpha is the lower bound of reliability and so may underestimate the true reliability. It is also argued that although alpha measures reliability, it is less able to measure construct validity as it is unable to distinguish whether the scale is measuring one construct (unidimensionality) or multiple constructs (multidimensionality), for which factor analysis may be appropriate(212).

A test-retest method, where the same test is administered to the same set of subjects some time apart(213, 214), was not used in this study to test for reliability due to financial constraints. The test-retest method also has problems as respondents may still remember the question if the time period between the two tests is too short. If the time period is too long, there may be changes in respondents attitudes and behaviours over time.

3.5.1.2.2 Challenges in sexual behaviour surveys

The studies by Kinsey of sexual behaviour provided an insight into the range of sexual behaviour(215). The emergence of HIV/AIDS in 1980s highlighted a need to understand sexual behaviour to influence the public health response to the epidemic. Sexual behaviour surveys continue to be important in understanding the epidemiology of these behaviours and to understand where public health actions need to be targeted.

Sexual behaviour surveys face particular challenges in ensuring high levels of validity and reliability. Sexual behaviour and reporting is subject to social and cultural desirability, which can challenge the generation of unbiased and precise measures of sexual behaviour(216, 217).

Measurement error can be caused by factors associated with sampling, recall, comprehension and willingness to report sensitive information(213, 216, 218). Several methods have been used historically to minimise measurement error. This section discusses some of the challenges in conducting sexual health surveys, methods that have been used to overcome these challenges and which of these methods have been employed in this study. It focuses on self-completion surveys as this is the method of data collection used in this study.

3.5.1.2.2.1 Study design and sampling

Four main groups of studies are used in sexual health surveys: general population surveys, sub-group surveys, partner and network studies and qualitative studies.

General population cross-sectional surveys can be used to estimate prevalence of behaviours in a population. Where probability sampling is used and response rates are high, this approach can provide an unbiased sample. Examples of this approach include the National Survey of Sexual Attitudes and Lifestyles (NATSAL)(219), which used a probability sampling technique to survey a representative sample of the general British population. Response rates for the NATSAL surveys have ranged between 60-70% and have all been broadly representative of the British population aged 16-59 years(220).

For smaller sub-groups, such as MSM, who may be harder to reach, cross-sectional surveys can give a snapshot of sexual health behaviour in that group. However, probability sampling is difficult in this group due to problems with access. Sampling from sexual health clinics has been widely used, but may not be representative of the wider population(216) and hence introduce selection bias. Studies suggest that MSM who attend sexual health clinics have higher risk behaviours than those that do not(221) and results from surveys sampling sexual health clinics may therefore overestimate sexual risk in the general population.

In both population and sub-group cross sectional surveys multiple surveys are required to monitor changes in behaviour over time. Temporal comparisons are influenced by changes in social, cultural and political norms that may have also changed over time and influence sexual behaviour(221), or populations may have changed. However, serial surveys have been successfully used at both population level(219) and for targeted subgroups to compare risk behaviour over time(221, 222).

Other designs that have been used in sexual health research include cohort studies. However, as the cohort population ages, age can confound the results. Younger age among MSM has been associated with higher risk sexual behaviour in several studies(221, 223), though results are

conflicting(224, 225). Selection bias may also be a challenge; individuals with higher sexual risk behaviours may either not join or drop out of longitudinal studies.

Partner studies in sexual health research have been used to identify risk factors for transmission, probabilities of transmission of infections and in understanding sexual networks(226-229). However, these studies are subject to selection bias, where those at highest risk may not be accessed. Sexual health studies are also subject to social desirability bias, where responses may be modified by the respondent to reflect social norms.

Ethnographic or qualitative studies have also been used to explore social contexts of sexual behaviour, transmission dynamics and cultural or social factors that influence sexual behaviour. Examples include understanding the importance of gay sex venues in transmission of HIV and STIs(230) and the acceptability of new biomedical interventions for HIV(231).

In this study a cross-sectional survey approach was used to recruit the target population from the sexual health clinic. This method allowed direct access to the target group, allowing for higher levels of participation. However, as mentioned earlier, this population may have higher risk sexual behaviours and so may not be representative of the general population. However, this study wanted to understand the drivers and barriers for service users in reattending for STI/HIV tests. Therefore it was appropriate to target service users through the sexual health clinic.

3.5.1.2.2.2   *Respondent factors*

Respondent factors can result in study errors and strategies are employed in the study design to reduce these.

An example is participation bias, which is the error that arises from systematic differences in the individual characteristics (such as sexual behaviour, sexual health history) of those that participate in a study compared to those that do not. How representative the study sample is of the source population is determined by the sampling frame, sample size and sample selection(208).

In sexual health research, some studies suggest that those with higher sexual risk behaviours are more willing to participate in studies(213, 216, 232-235).

Participation bias can be reduced by using probability sampling, where a sampling frame (e.g. census data) for the target population is used to try to obtain a sample as representative of the source population as possible. It is the most desirable form of sampling as it allows estimates of precision around the representativeness of the survey population to the source population. However, a sampling frame may not exist for harder to reach populations, such as MSM.

Participation bias can also be minimised by achieving high response rates, but this faces its own challenges depending on sampling design. Traditionally, higher response rates have been achieved using telephone or face-to-face interviews. Non-return rates of 40% or higher in postal surveys are not uncommon(213, 216, 233).   The sample should also be checked against source population demographics to check for representativeness. In this study, survey respondent demographics were compared to the clinic population where possible, and to the MSM population attending sexual health clinics in England using national surveillance data. A sensitivity analysis can also be used to take into account the different assumptions of bias(216, 234).

Social desirability bias refers to the tendency of respondents to give answers that they feel will be viewed positively by others or that fit with a social norm. In sexual health surveys, this can lead to underreporting of risky sexual behaviours. However, since sexual health survey participants are thought to have higher sexual risk behaviours (participation bias), this underreporting of sexual risk (social desirability bias) may make the responses more representative of the general population(216). However, Johnson et al found that participants disclosed high risk sexual behaviours more readily in self-completion surveys compared to face-to-face interviews(236). This survey attempted to reduce social desirability bias by using questions from validated questionnaires when asking about sexual health and lifestyle(237).

Problems in remembering details about sexual behaviour (recall bias) can make it difficult to estimate the frequency of those behaviours. Recall bias is influenced by number of sexual partners(213) and the time frame that is being asked about(238).

3.5.1.2.2.3 Questionnaire design factors

Pen and paper self-completion surveys face specific challenges that affect the quality of data that are captured. This form of survey can exclude those with poor literacy, participants have the option to skip questions, leading to missing data and poor comprehension may lead to data inconsistency(216).

3.5.2 In-depth interviews

The in-depth interviews were used to understand *how* reminders for HIV/STI testing influence reattendance and what the contextual factors are that influence these decisions. Topics that were explored were informed by the Theory of Planned Behaviour and explored sexual risk and lifestyle, HIV testing patterns and experience with and attitudes to healthcare reminders. Factors and attitudes that were associated with intention to reattend/re-test in the questionnaire survey were explored in the in-depth interviews to understand why, how and in what context they were associated.

The interviews aimed for breadth and depth of responses. Data were analysed using a form of thematic analysis. Descriptive and typological analyses were conducted to allow explanations for the association between attitudes to reminders and testing for HIV/STIs to be explored.

In developing the topic guide and planning the in-depth interviews, several methodological considerations were explored and these are outlined below.

3.5.2.1 Theory of qualitative methods

3.5.2.1.1 Philosophical approach

Qualitative research aims to understand underlying reasons, subjective perceptions, motivations and meanings of actions. Unlike quantitative research, it does not aim to understand the causal relationship between objectively measured phenomena. There are several different philosophical

approaches taken by qualitative interviewers that influence the methodological approach undertaken(207). This section briefly outlines the different philosophical questions that underpin this debate and then outlines the approach in this study.

Ontology

Ontology is concerned with the nature of the world and what there is to know about it. Central to the ontological debate is whether there is a social reality that exists independently of human beliefs or understanding.

In general, there are two broad ontological positions- realism and idealism. Realism supposes that there is an external reality that is independent of our beliefs and understanding.

Idealism supposes that the external reality is not independent of our beliefs and understandings. In idealism, the social world is open to subjective interpretation.

Epistemology

Epistemology is concerned with how we learn about the world and what the limits are to that knowledge. There are several epistemological approaches, the most common of which are positivism and interpretivism.

The positivist approach is quantitative. A hypothesis is tested and aims to discover relationships that are generalisable to the general population. It uses a mixture of inductive (bottom-up) and deductive (top-down) approaches.

The interpretivist approach aims to interpret people's perspectives in the context of the social and cultural aspects of their lives.

Approach in this thesis

Ontologically, this thesis takes the approach of 'subtle realism'(239), which suggests that an external reality exists that is independent of those who observe it (the researcher) but can be interpreted only through people's perceptions and interpretations (the participants). Therefore, the research

aimed to capture the complexity and depth of reality. Sampling is key to ensuring this complexity and depth is captured.

The framework analytical approach uses an interpretivist framework to understand people's perspectives in the context of the social and cultural aspects of their lives. It is important to understand participants' perception of behavioural control and social norms, as these factors influence how participants view the world. It uses a mixture of inductive and deductive technique, using existing theories to plan and design the study, but then uses a more grounded approach to seek detailed data. Towards the end of the analysis, research findings are often related back to existing theories and knowledge.

3.5.2.2 Types of qualitative research

This thesis used contextual research methods to explore what participants understand by active recall in the context of their social world and testing history. Explanatory research was used to try to understand some of the causal factors for repeat testing when a participant receives a reminder. Formative evaluative research was also used to understand the effectiveness of the text message reminder service in the service evaluation to shape the programme of active recall. Once the active recall programme is fully underway, qualitative methods can also be used for summative evaluative research to understand the impact of the programme.

3.5.2.3 Sample selection

Qualitative research uses non-probability sampling. Characteristics of the population are used to determine selection, and the aim is for depth and diversity of data. As a result, the sample selected may not be truly representative of the general population. This is in contrast to quantitative sampling, where the aim is to produce a statistically representative sample.

Key tenets of qualitative sampling are 'symbolic representation', i.e. the samples have features that are representative of the features that are relevant to the study. Secondly, the sample must be diverse to identify the full range of factors that are associated with the subject being studied and to allow the association between different factors that are associated with the study matter

to the investigated. For example, in this study, sexual behaviour may be associated with reattendance and so is intention to reattend. The study aimed to sample both factors with enough diversity to allow any association between the two to be investigated.

Approaches used in qualitative research include:

- Purposive sampling: Set criteria are used to select the sample based on particular features of characteristics, such as socio-demographic or behavioural factors. Within each of these features, participants are selected to ensure that there is diversity to allow the impact of the selection criteria to be explored. Depending on the aim of the study, sampling may aim for depth through homogeneous sampling, variation through heterogeneous sampling and extremes through deviant sampling(207). Purposive sample selection criteria are usually informed by literature and the study hypothesis.
- Theoretical sampling- Samples are selected to test a particular theoretical construct. Sampling is iterative; data are analysed and populations sampled to refine emerging theories. Sampling continues to data saturation, i.e. where further sampling would not result in new insights. Theoretical sampling is often used in grounded theory approaches to qualitative research.
- Convenience sampling- Samples are selected based on who is available. Convenience sampling restricts diversity and hence limits the validity of this approach. However it can be useful in early data collection.

More than one sampling strategy can be used in qualitative data collection. Often theoretical sampling is used at the start of an exploratory study to identify groups and characteristics to be included in later purposive samples(207). However, in this study, selection of the groups of interest was informed by the underlying theoretical framework and survey findings. Therefore, purposive sampling was used to ensure diversity.

The numbers of qualitative interviews required depends on ensuring diversity and representation. This is determined by the heterogeneity of the population

in relation to the subject matter, the number of selection criteria in the selection matrix and nesting of selection criteria (e.g. reattendance within sexual risk profiles), numbers of outliers or groups of special interests and resources available(240). In this study, two primary selection criterion (sexual risk behaviour and behavioural intention) were used to define the selection matrix and drive the numbers of interviews required.

3.5.2.4 Interviewing

The aim of in-depth interviewing is to gain breadth and depth in exploring the qualitative research question. Key features include use of open questions, supplemented by probes where necessary to draw out depth from the interviewee.

There are several different perspectives on in-depth interviewing based on the subject position of the researcher. For example, positivists argue that the interview participant has pre-existing knowledge or views, and the interviewer 'mines' to access these views(207, 241). Constructivists argue that knowledge is not pre-existing, but is generated along the course of the interview. In this case, the interviewer plays an integral part in the development of both data and meaning and the interview is seen as a journey(207, 241). A pragmatic view, taken in this thesis, is that interviews allow us to explore participants' understanding of phenomena beyond the context of the research environment; the interviewer is important in drawing out these meanings(207).

Some critics argue that interviewing is reflective of contemporary social and cultural norms or trends rather than the views of the participants themselves(207).

3.5.2.5 Analysis

This study used a form of thematic analysis outlined by Ritchie et al(207). It aims to find patterns and clusters of meaning within the data. In this thesis, analytic themes were grounded in the data at the start of the analytic process but theories influenced the design of the study and broad areas to be explored.

3.5.3 Mixed methods

This thesis used a mixed methods approach, making use of a quantitative questionnaire survey and qualitative in-depth interviews.

Mixed methods is the use of two or more different research methods to investigate a social phenomenon(242). This includes the use of quantitative and qualitative methods, but also two or more qualitative methods. This section focuses on the use of qualitative and quantitative methods.

In this thesis, findings from the quantitative and qualitative studies were integrated(242). Quantitative methods were used to understand the factors associated with intended and actual reattendance for HIV/STI testing and the preferred options for reminders. Qualitative methods were used to understand *how* reminders for HIV/STI testing influence reattendance and what the contextual factors are that influence these decisions.

There are several aspects of combining qualitative and quantitative methods. These include deciding the reason for integration- are the methods being combined to allow for triangulation, exploration or explanation? What sequence should the data be collected in? Should one method take priority? At what stage should the multi-methods approach take place- at the data collection, analysis or interpretation stage?(207, 243)

Justification for using mixed methods can be classified by the influential scheme proposed by Greene et al(243, 244). This outlines five justifications for combining quantitative and qualitative research:

1. Triangulation: seeking corroboration between quantitative and qualitative data to strengthen the validity of results(207, 242, 244). To enable this, both methods need to be measuring the same phenomenon and implemented simultaneously and independently of each other(244). However, there are debates about how well methods can validate each other. From an ontological perspective, it can be argued that there is no single conception of the social world, and so it is not possible to use multiple sources to validate each other.

Epistemologically, it is argued that each method yields a different type of data, and so cannot be concordant(207, 245).

2. Complementarity: Seeking an explanation or clarification from one method with results from another. However use of this approach, where one methods informs the other main method, has been criticised for not utilising the full potential of both quantitative and qualitative methods(245).
3. Development: uses the results from one method to inform or develop the other
4. Initiation: seeks new perspectives or questions to generate new hypotheses
5. Expansion: seeks to increase the breadth of data. However, it can also increase the depth or enhance the data by exploring other aspects such as contextual factors

The commonest purpose of mixed methods studies is complementarity or expansion(244). Typically, in expansion designs, process is measured by the qualitative measure and product or outcome by the quantitative measure.

The mixed methods approach was used in this thesis for expansion or exploration by asking two equally important but separate questions about the same topic to inform practice or policy. These are:

1. What are the factors associated with intention to reattend/re-test for HIV/STIs among MSM who receive an active recall reminder. This question is answered by the questionnaire survey.
2. How do active recall reminders influence intention to reattend/re-test for HIV/STIs among MSM. This question is answered by the in-depth interviews.

Neither method had priority in the approach used in this thesis, as they ask separate equally weighted questions.

The sequencing of quantitative and qualitative data collection is determined by the questions being asked of each method. Qualitative research traditionally precedes quantitative research where the subject is new and

qualitative data can help to define concepts, to generate hypotheses or to describe the population to allow for sample selection.

Both methods can also be used in tandem and this approach is used where the factors that underlie a phenomenon need to be explored, for example the drivers and barriers that underlie why people retest for HIV. Both methods are also used in tandem where different information is needed about the same phenomenon, for example measuring the proportion of participants who reattend for HIV/STI testing and understanding why they reattend. Finally, this approach is useful in understanding the context in which a phenomenon occurs.

Qualitative data collection can be useful in follow up to quantitative research where more detail or depth about a particular phenomenon that has been identified in the quantitative data collection is required.

In this study, in-tandem sequencing was used as it asks two separate but allied questions of the phenomenon in question, as outlined above.

There are several different approaches to analysis of mixed methods data. One approach is to analyse each dataset within its own parameters but to ask the same analytical questions of each one. Another approach uses a grounded inductive approach to lead the analysis whilst keeping the focus of the quantitative data(242). Finally, both datasets can be analysed separately and integrated at the point of explanatory analysis. However, this approach is not always able to explore divergence in findings between the two data sources(242).

In this thesis, both datasets were analysed separately and integrated at the point of explanatory analysis. The reason for taking this approach is to allow findings from both analyses to inform the development of the final theoretical framework.

3.6 **Conclusion**

This chapter outlined the main research question for the thesis- what are the drivers and barriers to active recall for HIV and STI testing among men who have sex with men (MSM) of negative or unknown HIV status?

This chapter explored the methodological options available for each study and the reasons for the selecting the approach taken. In the subsequent chapters, further detail is provided on the methodology and results of each of the studies.

Chapter 4   Systematic literature review

4.1 Introduction

The background chapter (chapter 2) argued that active recall may increase reattendance rates and re-testing rates for HIV and sexually transmitted infections (STIs). Chapter 3 outlined the main aims and objectives of the thesis. This chapter determines whether the published literature provides evidence for the effectiveness of active recall using a systematic review and meta-analysis of the current literature. Both HIV and STIs are included in this review as lessons can be drawn from reminders for both. The results from this review have informed the topic guide developed for the in-depth interviews. The structure of this chapter follows Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines on reporting of systematic literature reviews(246).

4.2 Structured summary

Background

Active recall has been used to encourage retesting for HIV and STIs. However, its effectiveness in increasing reattendance/re-testing rates and detection of HIV and STIs is unclear.

Methods

A systematic review and meta-analysis of active recall for HIV and/or STI testing was conducted. Six electronic databases using terms for HIV, STIs, tests, and active recall (defined as a reminder to re-test for HIV/STIs) for randomised, non-randomised, and observational English-language studies published between 1983-2013 were searched. Outcomes included re-attendance/retesting rate and STI diagnosis at follow up.

Results

Of 5634 papers identified, 17 met the inclusion criteria. Of the 14 comparative studies, all but one demonstrated higher re-attendance/re-testing rates in the intervention group, but range was wide (range 17·5%-89%). Meta-analysis of nine randomised controlled trials (RCTs) found re-attendance/re-testing rates were significantly higher in the intervention versus control groups (pooled odds ratio (OR) 2·42 (95%CI 1·84-3·19). In a subgroup analysis, self-sampling increased re-testing compared to clinic testing (pooled OR 2·20 (95%CI 1·65-2·94). In observational studies SMS reminders increased re-testing compared to standard clinic care (pooled OR 2·19 (95%CI 1·46-3·29), but study estimates were highly heterogeneous (I^2=94%, p<0.001).

Conclusion

Active recall interventions are associated with higher reattendance/re-testing rates for HIV/STI. Although self-sampling and SMS reminders were associated with higher reattendance/re-testing rates in most studies, evidence is limited by the heterogeneity of study design and the quality of studies. Further work is needed to explore which active recall modality is clinically and cost effective and acceptable for HIV/STI screening.

4.3 **Background**

National guidelines in England recommend testing men who have sex with men (MSM) at high risk of STIs every three months for HIV and STIs(3). Modelling studies suggest that three-monthly testing is cost saving and could reduce the number of new HIV infections(4, 5). Despite this, cross-sectional survey data suggest that fewer than a quarter of MSM in England and Scotland have four or more HIV tests per year(6).

Reminders in healthcare improve attendance and re-attendance rates(7, 8). Reminders for STIs or HIV testing include short message service (SMS) text messages, emails, telephone calls or letters. Sending out a kit for home sample collection or testing is another option. National guidance recommends use of reminders for encouraging retesting of MSM who have been diagnosed with an STI, but only a quarter of sexual health clinics have a recall system in place.(9) Healthcare providers need to know which is the most effective approach to increase reattendance/re-testing rates before widespread implementation.

Several studies have examined the effectiveness of active recall for healthcare appointments in general(109). A review of interventions to increase rates of re-screening for Chlamydia found evidence for mailing rescreening kits to increase re-testing rates and for telephone reminders, but evidence for SMS reminders has been conflicting(111, 112).

The reason for the conflicting evidence may be related to barriers to reminders that may reduce their acceptability and effectiveness in increasing reattendance or retesting and need to be explored. Concerns regarding privacy, confidentiality, and data protection have led to some services providing opt in schemes(247).

SMS text message reminders have the potential to be a useful active recall intervention if efficacy can be demonstrated. It is an inexpensive, unobtrusive and simple way of reminding patients about healthcare appointments(248), but it is a relatively new technology within the healthcare field. In high-income

countries, 70-90% of people have a mobile phone subscription and this proportion is similar among all socio-economic groups(247).

Mailing rescreening kits, or self-sampling in which a patient takes his/her own sample, also has the potential to access individuals for whom accessing a service is a barrier. Self-sampling can increase uptake(121), but not necessarily frequency of testing(121, 249). Surveys of attitudes to self-sampling have highlighted barriers to self-sampling including timeliness of results, accuracy and lack of immediate professional support(124, 250).

4.4 **Objectives**

The aim of this review was to determine whether the published literature provides evidence for the effectiveness of active recall for HIV/STIs in patients who are HIV negative or of unknown status.

The specific objectives were:

1. To determine the impact of active recall on screening and rescreening rates for HIV/STIs overall
2. To determine the impact of different active recall modalities on screening and rescreening rates for HIV/STIs
3. To determine the impact of active recall strategies on detection of HIV/STIs at rescreen overall and by different recall modalities

4.5 **Methods**

4.5.1 **Eligibility criteria**
Inclusion criteria:

The PICO (population, intervention, comparison, outcome) framework(251) was used to guide the eligibility criteria. Studies of patients who were HIV negative or of unknown status were eligible for inclusion. All populations were included, including females and men who sex with women, since conclusions may be applicable to MSM populations. Studies from all countries were

included. Testing facilities included hospitals, sexual health clinics, general practice, community venues and home sampling/testing.

The intervention was active recall (as defined below). The comparator was no active recall, a reminder at the initial visit only or no comparator (in the case of non-comparative and cohort studies). For home sampling studies, the comparator was no home sampling; comparators could include a recall modality such as an email or text message, phone call or letter as the recall intervention was the home sampling kit.

The primary outcome of interest was the proportion of those recalled who re-attended or re-tested at least once. The secondary outcomes were additional infections among those re-tested (number of infections/number re-attended or re-tested) and infections detected among those recalled (number of infections/number recalled). This gives an idea of clinical and public health benefit, since clinical benefit may be high if the number of additional infections at re-test is high, but public health benefit will depend on the number of additional infections identified through active recall, in relation to the cost of the programme.

All randomised and non-randomised interventional and non-interventional study designs were included. Qualitative studies were excluded from this review.

Exclusion criteria:

Exclusion criteria included studies without a recall intervention, pre- and post-test counseling without a recall intervention, recall for current episodes of care including tests of cure, post-exposure prophylaxis and pre-exposure prophylaxis studies, review articles, conference abstracts, and news reviews.

DEFINITIONS

Active recall: reminder to return for or to have a repeat test or screen. This can take the form of a short message service (SMS), email, telephone call, letter, booking a repeat appointment at the initial visit, or sending out a test. A verbal reminder at the initial visit does not count as active recall

Driver: a factor that encourages or facilitates a person carrying out an action, either consciously or not.

Barrier: a factor that dissuades or prevents a person from carrying out an action, either consciously or not.

4.5.2 Information sources

Six databases were searched: Medline, Pubmed, Embase, Cinahl Plus, Psychinfo, and the Cochrane Database of Systematic Reviews limiting the search from 1983 up to the date of the final search on 6th December 2013, human studies, and English language studies.

4.5.3 Search

Search key words included HIV, terms for STIs, specific STIs including chlamydia and gonorrhoea, test, screen, terms for active recall, and the specific modes of active recall including SMS text message and telephone.

The search strategy consisted of the following terms:

1. HIV
2. STI OR sexually transmit* infection OR sexually transmit* disease OR Chlamydia OR gonorrh*
3. test* or screen*
4. remind* OR recall OR repeat* OR rescreen* OR text OR SMS OR short message service OR mobile OR email OR phone* OR mobile phone OR telephone
5. (1 OR 2) AND 3 AND 4

An example of the search string used and results obtained from the Cinahl Plus database is provided in the appendix (appendix 1.1)

4.5.4 Study selection

The databases were searched to generate a list of titles. A full title screen was performed by one reviewer to remove obviously irrelevant articles. Shortlisted titles underwent full abstract review and full papers were shortlisted using the eligibility criteria above. Full paper review was conducted to generate a final list of papers included in the review. The reference list of included papers was searched manually to identify any articles missed by the search strategy. A standard set of data was extracted from each paper included in the final inclusion list onto a data collection proforma. Although article selection was only conducted by one reviewer (MD), a second reviewer extracted the data independently and the outputs were compared. Any disagreements were resolved by joint review of the paper.

4.5.5 Risk of bias in individual studies

The NICE Public Health Methods Manual was used to assess the methodological quality of each study(252). This is a modification of the graphical appraisal tool for epidemiological studies (GATE) checklist for interventional and observational studies. This tool was chosen as it is intended for use in the development of public health guidance and allows for assessment of all study types. Both reviewers assessed each study and where items on the tool were ambiguous, agreement was reached and study-specific criteria was developed and applied.

Other commonly used validated quality assessment tools include GRADE(253), which is a system for grading the quality of evidence and the strength of recommendations that can be applied across a wide range of interventions and contexts. It grades the strength of each important outcome and looks at considerations around study design and study quality. It also takes into account values and preferences and considers the trade-offs between harms and benefits.

The NICE Public Health Methods tool was used in preference to the GRADE tool as it has assessment criteria specific to the development of public health

guidance in England. Therefore, there is more emphasis placed on external validity for England in comparison to the GRADE tool. However, where studies were conducted outside England or in a health system different to the English health system, this could result in downgrading of the quality of the paper due to limited external validity when using the NICE Public Health Methods tool.

The importance of using a tool that has been rigorously developed or tested for validity and reliability was highlighted in two systematic reviews. One systematic review that assessed tools for methodological quality for RCTs found 21 tools, but found that most were not rigorously tested for validity and reliability(254). A systematic review of tools for quality assessment of non-randomised studies found 182 different tools, but could only recommend six of them for use in systematic reviews(255).

4.5.6 Statistical analysis

Outcome data for reattendance/re-testing were pooled using a random effects model due to heterogeneity between studies and study samples using the Stata® statistical package(256, 257). Pooled odds ratios (OR) are presented separately for randomised controlled trials and observational studies, since biases inherent to observational studies may affect the RCT results. Pooled OR for each active recall intervention is presented separately and as an overall pooled estimate. Each of the studies followed up participants over different time periods; both crude and pooled odds ratios are presented, but the heterogeneity of studies is also considered. Heterogeneity of study population was controlled for as far as possible by presenting results for studies with two distinct comparison groups, such as a concurrent and historical control group or control groups from two independent populations separately.

Publication bias was assessed with a funnel plot and using the Harbord test of small study sizes(258).

Factors associated with reattendance/re-testing are presented descriptively, with population sub-group analyses where possible (e.g. by gender, sexual orientation).

4.6 Results

4.6.1 Search results

The electronic search identified 5634 unique citations. Title and abstract screening identified 45 citations as potentially eligible for the review and full text was retrieved for these studies. Twenty-eight studies were excluded for reasons outlined in the appendix (appendix 1.1). Seventeen studies met the eligibility criteria (figure 6).

Figure 6: Flow diagram of systematic literature review search
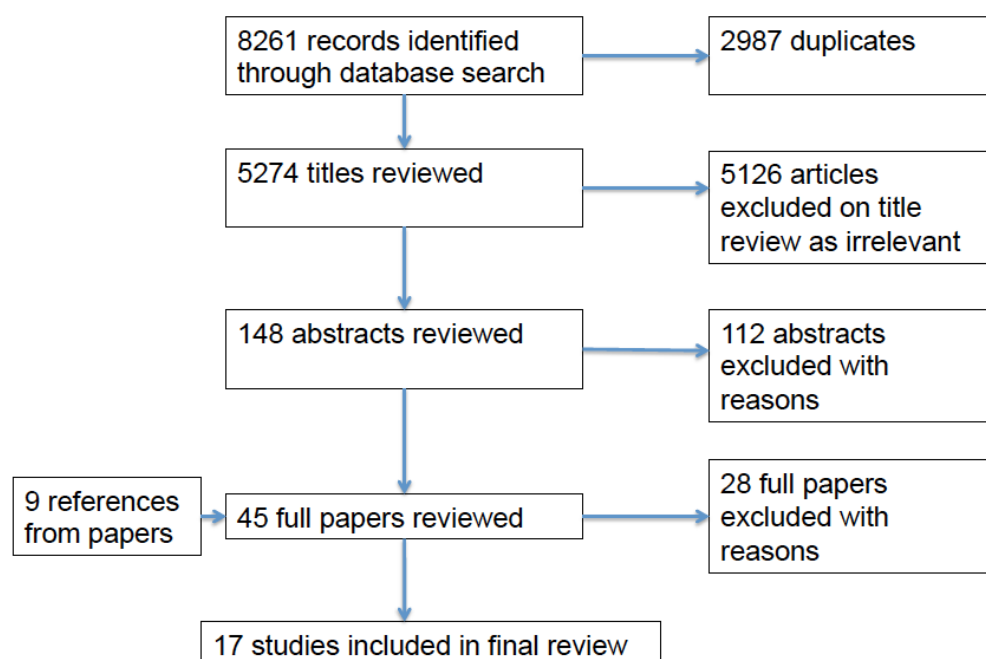
Study design and intervention (table 2& 3): Six were randomised controlled trials (four home sampling, one phone call reminder and one SMS reminder). Two of the home sampling studies used a phone call reminder and one used an email reminder in addition to sending the kit. Eleven studies were observational with an intervention, including non-randomised before and after controlled studies (n=5), non-comparative studies (n=4) and cohort studies (n=2). Non-comparative studies included cross-sectional studies and service evaluations. Four used an SMS reminder, one used a postcard/letter, one used a phone call and five used a home sampling kit. One of the home sampling kit studies used a telephone reminder in addition to sending the kit.

Comparator: All comparator arms for the home sampling randomised control studies used either a phone call, email or postcard reminder in addition to the offer of a test at a clinic.

Populations: Three studies were conducted among MSM only, two included MSM among other male and female populations, five included females only and the remainder included males and females.

Geography: Two studies were conducted in the Netherlands(172, 259), four in the UK(77, 260-262), five in Australia(263-267) and the remainder in the USA(171, 268-272).

Table 2: Study characteristics for randomised controlled trials

STUDY	SETTING	STUDY POPULATION	STUDY CHARACTERISTICS		
	- Clinic/ community - Country	- Gender - Sexual orientation - Selection criteria for recall - Recall test - HIV status - Number (N)	Intervention	Control	Recall interval[1]
Type of intervention: send home sampling kit					
Sparks et al STD 2004(268)	ClinicUSA	- M (66%) in clinic group, F (33%)M (72%) in mail/clinic group, F (18%) - heterosexual - Chlamydia or gonorrhoea diagnosis - Chlamydia/ gonorrhoea test - HIV status not specified - Number= 122	Choice of home sampling or clinic retest with telephone/mail reminder	Clinic retest only with telephone/mail reminder	10 weeks[4]
Xu et al Obstetr Gynacol 2011(269)	Clinic USA	- Female - sexual orientation not specified - Chlamydia diagnosis - Chlamydia test - HIV negative or unknown status - Number= 1215	Home sampling kit mailed or pick up from clinic + phone call reminder	Clinic appointment + phone call reminder	3 months
Gotz et al BMC Infect Dis 2013(259)	Clinic Netherlands	- M (30%), F (70%) heterosexual - Chlamydia diagnosis - Chlamydia test - HIV negative - Number= 216	Email reminder + home sampling kit	Email reminder + clinic retest	4-5 months
Cook et al STIJ 2007(270)	Clinic & community USA	- Female - sexual orientation not specified - Chlamydia, gonorrhoea or	Home sampling kit mailed or pick up from clinic	Postcard reminder	6,12,18 months after recruitment

		trichomonas diagnosis - Chlamydia/ gonorrhoea test - HIV status not specified - Number= 388			
Type of intervention: Phone call/ letter					
Malotte et al STD 2004 USA(171)	Clinic USA	- M (43.7%), F (56.3%) - sexual orientation not specified - Chlamydia or gonorrhoea diagnosis - STD screen - HIV status not specified - Number= 499	Group 2:Appointment card+ verbal advice + financial incentive Group 3:Motivational counselling at baseline + phone call reminder at 3 months or letter Group 5:Appointment card + verbal advice + phone call reminder at 3 months Group 6:Motivational counselling at baseline, no reminder	Standard care (verbal advice): Groups 1 & 4	3 months
Type of intervention: SMS					
Downing et al STIJ 2013(112)	Clinic Australia	- M(48.9%), F(51.1%) - sexual orientation not reported - Chlamydia diagnosis - Chlamydia test - HIV negative or unknown - Number = 94	Standard advice + SMS reminder +/- financial incentive	Standard care (verbal advice)	10-12 weeks

1. Recall interval is the time between baseline visit and reminder being sent/received. It does not include the window period in which reattendance was counted

Table 3: Study characteristics for observational studies

STUDY	SETTING	STUDY POPULATION	STUDY CHARACTERISTICS			
	- Clinic/ community - Country	- Gender - Sexual orientation - Selection criteria for recall - Recall test - HIV status - Number (N)	Study design	Intervention	Control	Recall interval
Type of intervention: SMS						
Bourne et al STIJ 2011(168)	Clinic Australia	- Male - MSM - High risk sexual behavior - HIV/STI screen - HIV negative - Number = 3551	Non randomised before-after study	SMS	1. Concurrent control 2. Historic control	4 months
Zou et al PLoS One 2013(265)	Clinic Australia	- Male - MSM - All MSM - Syphilis test - HIV status not specified - Number = 4179	Non randomised before-after study	SMS or email	1. Concurrent control 2. Historic control	3/6/12 months
Burton et al STIJ 2013(260)	Clinic UK	- M (243/539: 45%), F (296/539: 55%) - Heterosexual, MSM - Patients at higher risk of STIs and in HIV window period - HIV/STI screen - HIV status not specified	Non randomised before-after study	SMS	Historic control	4 months

		- Number = 539				
Guy et al STIJ 2013(111)	Clinic Australia	- M (192/343: 56%), F (151/343: 44.0%) - Heterosexual - Chlamydial infection - Chlamydia test - HIV status not specified - Number = 681	Non randomised before-after study	SMS	1. Concurrent control 2. Historic control	3 months
Type of intervention: Postcard/letter						
Paneth-Pollack et al STD 2010(271)	Clinic USA	- M (4168/6220: 67%), F (2079/6220: 33%) - All sexual orientation - Chlamydia or gonorrhoea diagnosis - Chlamydia/gonorrhea test - HIV status not specified - Number = 6220	Non randomised before-after study	Postcard	1. Standard care in non-intervention clinics 2. Historic control	3 months
Type of intervention: Phone						
Harte et al STIJ 2011(77)	Clinic UK	- Male - MSM - Diagnosis with acute bacterial STI (chlamydia, gonorrhoea, syphilis, LGV) - HIV/STI screen - HIV positive and negative - Number = 301	Non-comparative study	Phone	N/A	3 months
Type of intervention: send home sampling kit						

Bloomfield et al STIJ 2003(272)	Clinic USA	- M (186/312: 59%), F (127/312: 41%)MSM (57/312: 18%) - Chlamydia diagnosis - Chlamydia test - HIV status not specified - Number = 399	Non-comparative study	Mailed home sampling kit	N/A	1-6 months
Gotz et al STIJ 2013(172)	Community Netherlands	- M (1177/4191: 28%); F (3014/4191: 72%) - sexual orientation not specified - Chlamydia diagnosis - Chlamydia test - HIV status not specified - Number = 4191	Cohort	home sampling kit mailed	n/a	6 months
LaMontagne et al STIJ 2007(261)	Clinic UK	- Female - Chlamydia diagnosis - Chlamydia test - HIV status not specified - Number = 592	Non-comparative study	home sampling kit mailed	N/A	3 months
Walker et al PLoS One 2012(267)	Community Australia	- Female - Chlamydia diagnosis - Chlamydia test - HIV status not specified - Number = 1116	Prospective cohort	home sampling kit mailed	N/A	3 months if STI 6 and 12 months for everyone
Cameron et al Hum Reprod 2009(262)	Community UK	- Female - Chlamydia diagnosis - Chlamydia test - HIV status not specified - Number = 330	Non-comparative study	home sampling kit mailed and telephone reminder	N/A	3 months

4.6.2 Risk of bias

Appendix tables 17 and 18 show the methodological quality of included interventional studies. Of the six randomised control trials, one was assessed as having all of the criteria of internal validity fulfilled (++: high quality study)(270) and the remainder fulfilled some of the criteria (+: moderate quality study). The moderate quality RCTs were not adequately blinded, were underpowered or did not account for all sources of potential bias e.g. baseline characteristics, sexual risk. Only one RCT was assessed as having adequate (+) external validity(263).

Of the controlled before and after studies, all were felt to have only adequate (+: moderate quality study) internal validity due to not being randomised (and hence unable to minimise allocation or selection bias); some did not adjust for potential confounders at analysis. All were assessed as having low external validity (-).

Of the included observational studies, one was felt to have high (++: high quality study) internal validity and the remainder adequate (+: moderate quality study) internal validity. Reasons included potential selection bias due to ghost addresses and systematic differences in baseline characteristics between included and excluded groups. All were assessed as having low external validity (-), mainly because the source population was not clearly identified and hence findings could not be generalised.

4.6.3 Reattendance rates

4.6.3.1 Overall

Overall, use of active recall increased reattendance/retesting. All but one study of active recall with high or moderate internal validity (high/moderate quality study) demonstrated high reattendance/re-testing rates in the intervention group; however the range of reattendance rates was wide, from 17%(272)-89%(265). Among all active recall interventions, the odds ratio for reattendance in the intervention group compared to the control group ranged from 0·93 (95% CI 0·65, 1·33) to 14·0 (95% CI 1·63, 120·1).

The pooled OR for reattendance/retesting in the six RCTs was 2·42 (95%CI 1·84, 3·19) and had low heterogeneity (I^2=38%, p=0·12) among 2,400 participants (table 4, figure 7).

The pooled OR for reattendance/retesting in the observational studies was 2·13 (95%CI 1·54, 2·93) but had high heterogeneity (I^2=93%, p<0.001) among 18,289 participants (table 5, figure 8).

Figure 7: Forest plot of odds ratio of reattendance/re-test in randomised controlled trials of active recall for HIV/STI screening

Study ID	OR (95% CI)	Events, Treatment	Events, Control
Home_sampling			
Sparks	1.72 (0.82, 3.59)	27/60	20/62
Xu (STI clinic)	1.54 (1.11, 2.15)	109/408	77/403
Xu (Family Planning clinic)	2.65 (1.70, 4.11)	80/196	43/208
Gotz	2.78 (1.55, 4.99)	50/109	25/107
Cook	2.83 (1.78, 4.50)	161/197	117/191
Subtotal (I-squared = 43.8%, p = 0.130)	2.20 (1.65, 2.94)	427/970	282/971
Phone			
Malotte (phone call)	14.00 (1.63, 120.09)	9/27	1/29
Malotte (counselling +phone call)	2.50 (1.30, 4.80)	33/136	16/141
Subtotal (I-squared = 56.5%, p = 0.129)	4.34 (0.89, 21.23)	42/163	17/170
SMS			
Downing (SMS only)	5.87 (1.16, 29.83)	9/32	2/32
Downing (SMS +financial incentive)	5.45 (1.05, 28.24)	8/30	2/32
Subtotal (I-squared = 0.0%, p = 0.950)	5.66 (1.78, 17.99)	17/62	4/64
Overall (I-squared = 37.5%, p = 0.119)	2.42 (1.84, 3.19)	486/1195	303/1205

NOTE: Weights are from random effects analysis

.00833   1   120

Table 4: Summary table of reattendance/retest outcome for randomised control trials

STUDY	OUTCOMES		
	Reattendance (number reattending /number reminded to retest)		
	Reattendance in intervention group	Reattendance in control group	Crude OR (95% CI), statistical finding[3] (ITT analysis, unless otherwise stated)
	n/N (%)	n/N (%)	
Type of intervention: send home sampling kit			
Gotz et al BMC Infect Dis 2013(259)	50/109 (46%)	25/107 (23%)	OR 2.8 (95% CI 1.5,5.0)
Sparks et al STD 2004(268)[2]	27/60 (45%)	20/62 (32%)	OR 1.7 (95% CI 0.8,3.8)
Xu et al Obstetr Gynacol 2011(269)	STI Clinic recruits: 109/408 (26.7%) Family planning recruits: 80/196 (40.8%)	STI clinic recruits: 77/403 (19.1%) FP recruits: 43/208 (20.7%)	STI clinic group: Calculated OR= 1.5 (calc 95% CI 1.1, 2.2) FP group: Calculated OR= 2.6 (calc 95% CI 1.7, 4.2)
Cook et al STIJ 2007(270)	/197[3] (82%)	/191 (61.3%)	N/A
Type of intervention: Phone call/ letter			
Malotte et al STD 2004 USA(171)[1]	Group 2 Financial incentive: /141 (13.2%) Group 3 MI+ reminder: /136 (23.9%) Group 5 Reminder only: /27 (33%) Group 6 MI only: /25 (12%)	Group 1: /141 (11.4%) Group 4: /29 (3.4%)	Compared to group 1: Group2: OR 1.2 (95% CI 0.6, 2.4) Group3: OR 2.5 (95% CI 1.3, 4.8) Crude OR not reported for group 5 vs 4 or group 6 vs 4. After controlling for gender and STD test in the last year: Compared to group 4: Group 5: OR 12.3 (95% CI 1.4, 112.0) Group 6: OR 2.5 (95% CI 0.2, 28.0)
Type of intervention: SMS			

Downing et al STIJ 2013(112)	SMS reminder only: 9/32 (28.1%) SMS + financial incentive: 8/30 (26.7%)	2/32 (6.3%)	SMS reminder only: Calculated OR= 5.9 (calc 95% CI 1.0, 59.4) SMS + financial incentive: Calculated OR= 5.4 (calc 95% CI 0.9, 56.1)

1. Where no numerator is given in the paper, the denominator is presented for completeness

2. In Sparks et al, retest within the 28 day window period after recall is presented as this is more likely to be associated with the recall than retests in the 100 day window period

3. OR and 95% CI is calculated where not provided in the paper and is specified as 'calc OR' or 'calc 95% CI'

Figure 8: Forest plot of odds ratio of reattendance/re-test in observational studies of active recall for HIV/STI testing

Study ID	OR (95% CI)	Events, Treatment	Events, Control
SMS			
Bourne (concurrent control)	4.29 (3.50, 5.24)	460/714	322/1084
Bourne (historical control)	4.04 (3.36, 4.85)	460/714	543/1753
Zou (concurrent control)	3.26 (2.60, 4.10)	885/997	978/1382
Zou (historical control)	1.88 (1.50, 2.36)	885/997	1454/1800
Burton	0.93 (0.65, 1.33)	90/273	92/266
Guy (concurrent control)	1.29 (0.80, 2.09)	42/141	50/202
Guy (historical control)	1.60 (1.02, 2.49)	42/141	71/338
Subtotal (I-squared = 93.9%, p = 0.000)	2.19 (1.46, 3.29)	2864/3977	3510/6825
Postcard			
Paneth-Pollack (concurrent control)	2.04 (1.67, 2.49)	179/1267	288/3861
Paneth-Polack (historical control)	1.75 (1.34, 2.27)	179/1267	94/1092
Subtotal (I-squared = 0.0%, p = 0.354)	1.93 (1.65, 2.26)	358/2534	382/4953
Overall (I-squared = 93.1%, p = 0.000)	2.13 (1.54, 2.94)	3222/6511	3892/11778

NOTE: Weights are from random effects analysis

.191   1   5.24

Table 5: Summary table of reattendance/retest outcome for observational studies

STUDY	OUTCOMES		
	Reattendance (number reattending /number reminded to retest)		
	Reattendance in intervention group	Reattendance in control group	Crude OR (95% CI), statistical finding[3]
	n/N (%)	n/N (%)	
Type of intervention: SMS			
Bourne et al STIJ 2011(168)	460/714 (64%)[1]	1. Concurrent control: 322/1084 (29.7%) 2. Pre-intervention group: 543/1753 (31%)	1: Concurrent control: 4.5 (calc 95% CI 3.5-5.5) 2. Historical control: 3.1 (calc 95% CI 2.5-3.8)
Zou et al PLoS One 2013(265)	885/997 (89%)	1. Concurrent control: 978/1382 (70.8%) 2. Historic control: 1454/1800 (80.8%)	1. Concurrent control: calculated OR= 3.3 (calc 95% CI 2.6, 4.1) 2. Historic control: calculated OR= 1.9 (calc 95% CI 1.5, 2.4)
Burton et al STIJ 2013(260)	90/273 (33%)	92/266 (35%)	Calculated OR= 0.93 (calc 95% CI 0.65-1.33)
Guy et al STIJ 2013(111)	42/141 (30%)	1. Concurrent control: 50/202 (25%) 2. Historic control:71/338 (21%)	1:Concurrent control:1.26 (95% CI 0.78-2.06) 2. Historical control: 1.57 (95% CI 1.01-2.46)
Type of intervention: Postcard/letter			
Paneth-Pollack et al STD 2010(271)	179/1267 (14.1%)	1. Non-intervention group: 288/3861 (7.5%) 2. Pre-intervention: 94/1092 (8.6%)	1. Non-intervention: calculated OR= 2.0 (calc 95% CI 1.7, 2.5) 2. Pre-intervention: calculated OR= 1.7 (calc 95% CI 1.3, 2.3)
Type of intervention: Phone			
Harte et al STIJ 2011(77)	206/301 (68%)	N/A	N/A

Type of intervention: send home sampling kit			
Bloomfield et alSTIJ 2003(272)	70/399 (17.5%)[2]	N/A	N/A
Gotz et al STIJ 2013(172)	2777/4191 (66.3%)	N/A	N/A
LaMontagne et al STIJ 2007(261)	417/592 (70.4%)	N/A	N/A
Walker et al PLoS One 2012(267)	3 months: 40/55 (73%) 6 months: 889/1116 (80%) 12 months: 887/1116 (79%)	N/A	N/A
Cameron et al Hum Reprod 2009(262)	215/330 (65%)	N/A	N/A

1. Data obtained from author
2. 399 is used as the denominator in the paper by Bloomfield et al as this is the number that were invited. Ghost addresses and refusals were then taken out. This allows for consistency with the other included studies.
3. OR and 95% CI is calculated where not provided in the paper and is specified as 'calc OR' or 'calc 95% CI'

4.6.3.2 SMS

Five studies used SMS as the active recall intervention(260, 263-266). Among SMS reminder intervention groups, the OR of reattendance/retesting compared to clinic control groups ranged between 0·93 (95% CI 0·65, 1·33)(260) and 5·87 (95% CI 1·16, 29·83)(263) .The pooled OR among the observational studies was 2·19 (95%CI 1·47, 3·23) but had high heterogeneity (I^2=93%, p<0.001). A pooled OR for reattendance among the SMS group was derived from two RCT sub-studies of different interventions (SMS only and SMS+financial incentive) reported in one paper and was 5·66 (95% CI 1·78, 17·99) among 126 participants and had low heterogeneity (I^2=0·0%, p=0·95) (263). However, although this study was of high methodological quality, populations were recruited from the same clinic population and sample sizes were very small(263).

4.6.3.3 Phone call reminders

One study used phone calls as an active recall intervention(171). Two groups received a phone call reminder in addition to verbal advice and counseling. Both groups saw higher reattendance compared to controls who received verbal advice only. The OR for the phone call reminder+ verbal advice + counseling group was 2·50 (95% CI 1·3, 4·8) and the OR for the phone call reminder + verbal advice group was 14·0 (95% CI 1·63-120·09) (table 4, figure 7). The pooled OR for reattendance among the phone call group was 4.34 (95% CI 0.89, 21.23) among 170 participants and had moderate heterogeneity (I^2=56.5%, p=0·13). However this study had poor internal and external validity, was not powered to show an effect, the control arm included an intervention that was not standard care, and there was little information about the representativeness of the study population in relation to the source.

4.6.3.4 Self sampling kit

Four RCTs(259, 268-270) and five observational studies(172, 261, 262, 267, 272) assessed the impact of sending self sampling kits on retesting rates. The four RCTs sent out a self sampling kit combined with a phone call/email reminder and had a comparison group, which included clinic appointment + phone call/email/postcard reminder. The observational studies did not have comparator arms.

Among the four RCT, retest rates in the self sampling groups ranged from 1·54 (95% CI 1·11, 2·15)(269) to 2.83 (95% CI 1·78, 4·50)(270). The pooled OR was 2.20 (1·65, 2·94) across 1942 participants and had low heterogeneity (I^2=44%, p=0·13).

4.6.4 Clinical outcome

Four RCTs reported chlamydia infection rates(259, 263, 269, 273) at retest as the clinical outcome, one reported chlamydia and gonorrhoea infection at retest(268) and one looked at STIs in general(270) (appendix table 19 and 20). Three observational studies reported acute bacterial STIs (chlamydia, gonorrhoea, syphilis and LGV) and HIV (SMS reminders as the active recall)(77, 260, 265), five reported chlamydia reinfection (all self sampling studies)(172, 261, 262, 267, 272), one reported chlamydia and gonorrhoea reinfection (postcard/letter as the active recall)(271) and two did not report a clinical outcome(264, 266).

Two RCTs reported clinical outcomes that allowed OR of infections in the intervention group compared to the control group to be calculated(259, 269). Both compared self-sampling kit intervention with email/phone reminder to clinic care. The OR of testing positive at the re-test visit in intervention versus control groups ranged between 0.7 (95%CI 0·3, 1·5) and 0.9 (95%CI 0·3, 2·6) among those re-tested, and between 0·9 (95%CI 0·4, 1·8) and 1·6 (0·4, 6·5) among those recalled.

4.6.5 Factors associated with reattendance/re-test

In this review, in studies that included both men and women, women were more likely to retest than men(259, 271). Those men and women who were younger, had more sexual partners or had a lower education level were less likely to retest(172, 259). Among studies that only included MSM, reattendance was associated with some conflicting factors e.g. reattenders were more likely to have higher sexual risk (e.g. higher number of partners) but also have higher condom use(265).

4.6.6 Assessment of publication bias

A funnel plot of RCTs shows symmetry for the self-sampling studies (appendix figure 14). The Harbord test for small study size effect suggests

that there is no small study size effect (p=0·520). The SMS interventions and phone call studies are too few to comment upon.

A funnel plot of observational studies suggests some asymmetry with lack of small studies showing a large effect size for SMS interventions (appendix figure 15). The Harbord test for small study size suggests no small study size effect (p=0·063). There are too few postcard and no self sampling studies to comment on these intervention types.

4.7 DISCUSSION

The studies in this review provide evidence for the use of active recall in increasing or achieving high reattendance/retesting rates for testing for HIV/STIs. Although the review suggests that self-sampling and SMS are associated with higher rates of reattendance/re-testing, evidence is limited by heterogeneity of interventions and control groups and the quality of studies. There were too few studies to assess the impact of other interventions. The results do not provide clear evidence to support any one active recall intervention over another.

Furthermore, the time interval to recall and indication for recall varied across the studies, making it difficult to draw conclusions about which time interval and indication is the most effective in increasing reattendance/re-testing rates when using recall.

It was not possible to determine the impact of active recall on detection of STI reinfection as only two RCTs compared infection rates between the intervention and control groups. Although both studies suggest no difference in infection rates between the control and intervention groups, they have wide non-significant confidence intervals.

These findings are in agreement with other systematic reviews of active recall to improve reattendance rates for healthcare appointments, vaccinations and other diseases such as tuberculosis and health promotion(7, 8, 109, 274), which have demonstrated net benefit. Several reasons have been given for

missed appointments, including forgetting, and the use of a reminder can help facilitate reattendance(275, 276).

A review by Car et al found that SMS reminders increased the rate of attendance at healthcare appointments compared to no reminders (risk ratio (RR) 1·10 (95% CI 1·03 to 1·17). Cost per attendance for SMS reminders was lower than phone reminders(109). SMS has been successfully used in health promotion, and a recent meta-analysis suggested a net benefit of SMS on health outcomes(274).

Reattendance among MSM in this review was associated with higher number of partners and higher condom use, which may reflect higher self-perceived risk and greater awareness of sexual health(265). This demonstrates features of both regular and repeat testers as outlined in chapter 2. In this review, non-reattenders in response to recall were more likely to be HIV positive(77), in keeping with studies that have compared sexual risk among those that test for HIV compared to those that do not(42, 77, 277).

The Theory of Planned Behaviour(166) suggests that social norms, behavioural attitudes, and perceived behavioural control influence an individual's behavioural intention to test. In the case of HIV/STI screening, active recall may influence behavioural attitudes and perceived behavioural control to empower an individual to take control of their sexual health and change their testing behaviour, changing their probability of reattendance. Few studies explore the drivers and barriers to active recall for HIV/STI recall, and those that do highlight concerns regarding the confidentiality and sensitivity of active recall reminders and the importance of framing the message correctly. Qualitative studies highlight the importance of using messages to increase risk perception and motivational messages to reduce fear of getting tested(278).

If active recall for HIV/STI testing is an effective method to increase reattendance rates, as is suggested by this review, the most cost-effective strategy needs to be determined. One study assessed cost-effectiveness of phone call reminders and found brief verbal advice combined with a phone reminder yielded the highest return rate and the lowest cost per infection

treated compared to brief verbal advice alone or a financial incentive(279). Other studies suggest that the use of SMS reminders is a cheap and effective way of increasing reattendance rates for HIV/STI testing, but no cost-effectiveness studies were performed.

4.7.1 Limitations

The inclusion criteria were kept broad to include as many relevant studies as possible. However this resulted in variation in the odds ratio for reattendance attributable to heterogeneity for some intervention types. This may be due to differences in study populations and different follow up times.

Secondly, the low methodological quality of the majority of the included studies means that it is difficult to draw conclusions about any of the individual active recall intervention types. Participants in studies of active recall reminders cannot be blinded to the intervention they receive; this results in these studies receiving a low score for internal validity due to the potential for selection and participation bias. Several studies included multiple interventions or did not have a standard care comparison, making it difficult to unpick individual intervention effects.

None of the studies scored highly for external validity because it was not possible to assess representativeness of the source population to the general population.

Finally, all studies were conducted in high-income countries and the results may not be applicable to lower-income settings. Social norms may differ in different cultural contexts and could influence the ability of reminders to increase reattendance rates for HIV and STI testing.

4.8 CONCLUSIONS

This systematic review suggests that active recall interventions are associated with an increase in re-testing rates for HIV/STIs. However, the evidence is limited by heterogeneity of interventions and control groups and therefore cannot determine which method of active recall is most effective, although

there is some suggestion that SMS reminders are associated with higher reattendance/retesting rates.

An adequately powered randomised control trial comparing the different methods of active recall is needed to assess the efficacy of the different active recall interventions, their cost-effectiveness and acceptability as well as drivers and barriers to returning for an HIV/STI screen when actively recalled.

The next chapter (chapter 5) assesses whether an active recall intervention for HIV negative/unknown HIV status MSM using SMS reminders increases reattendance rates and adds to the systematic literature reviewed in this chapter.

.

Chapter 5   Study 1: Service development and evaluation of active recall for HIV/STI testing

5.1 Introduction

The systematic literature review in chapter 4 suggested that active recall interventions are associated with an increase in re-testing rates for HIV/STIs. There was some suggestion that short message service (SMS) text reminders are associated with higher reattendance/re-testing rates compared to no active recall.

At Mortimer Market Centre, SMS reminders are routinely used to actively recall MSM diagnosed with an acute bacterial STI for a repeat HIV/STI screen. As a service development, the use of SMS active recall reminders for HIV/STI screening was extended to include all MSM reporting unprotected anal sex (UAI) in the past three months, since they are at high risk of HIV and other sexually transmitted infections (STIs). This service was evaluated to determine whether introduction of an SMS active recall reminder for MSM reporting UAI would increase reattendance rates.

This chapter outlines the service development and results of the evaluation of SMS active recall for HIV/STI testing.

5.2 Background

National guidelines recommend the use of SMS reminders to actively recall MSM diagnosed with a STI for STI testing three months after their initial visit(3). SMS reminders have been successfully introduced at Mortimer Market Clinic targeting this group (77, 280).

MSM who report UAI are at high risk of infection with HIV and other STIs. National guidance recommends three-monthly HIV testing for this group. The reattendance rate for this group at Mortimer Market Clinic has historically been low. In 2011, 862 MSM, who reported UAI with a man in the past three

months and who were not infected with a bacterial STI, attended clinic over a three-month period. Of these 862 MSM, 132 (15%) reattended the service within four months after their initial visit (unpublished data).

In 2012 a service development was implemented to actively recall MSM for a HIV/STI screen three months after their initial test. MSM were eligible to be recalled in the service development if they reported UAI with a man in the past three months, were aged 16 and above and were HIV negative or of unknown status. These MSM were actively recalled using an SMS reminder. MSM who were offered post-exposure HIV prophylaxis, were taking part in a trial of pre-exposure prophylaxis, were diagnosed with HIV or were diagnosed with an acute bacterial STI were not eligible to be recalled in the service development as they already receive an active recall reminder. Patient information leaflets outlining the rationale for the service development were made available in clinic (appendix figure 16).

The implementation of the service development was an iterative process. The process used the Programme Science methodology and a 'Plan,Do,Study,Act' (PDSA) approach(281). As a result there were three distinct periods of operation of the recall intervention:

1. Period 1 (SMS introduction):
   Visit period: 1st September 2012- 31st November 2012
   Reattendance period: 1st December 2012- 1st May 2013

   Clinicians identified MSM reporting UAI with a man in the past three months during sexual risk assessment in routine clinic consultations. Clinicians added these MSM to an SMS recall list manually. However, only 31 of 687 eligible MSM (4.51%) were recorded in the electronic patient records (EPR) system by clinicians as requiring an SMS recall reminder. It was thought that a barrier to recall may have been clinicians not identifying and adding eligible MSM onto the recall list.

2. Period 2 (mandatory consent field):
   Visit period: 1st September 2013- 31st December 2013

To ensure that clinicians asked all eligible MSM if they wanted to be recalled, a pop-up box was introduced into the EPR system instructing clinicians to consent eligible patients for recall. The pop-up box was triggered if a MSM reported UAI in the past three months. The introduction of the pop-up box ensured that all eligible patients were identified. However consenting patients only received an SMS reminder if clinicians added consenting patients to the recall list manually. Almost 40% (438/1112) of eligible MSM were recorded as having consented to recall, but only 49 (4.41% of the eligible group, 11.1% of the consenting group) were placed on the recall list. Therefore it was thought that the barrier to recall was now transfer of eligible and consenting MSM to the recall list. There was no reattendance period as the third period was introduced immediately.

3. Period 3 (semi-automated transfer to recall list):
   Visit period: 1st January 2014- 31st March 2014
   Reattendance period: 1st April 2014- 1st September 2014

   A list of all eligible MSM who consented to recall was automatically generated from the EPR on a monthly basis. This list was manually transferred onto the recall list by an administrator. This ensured that all eligible MSM were identified and all eligible and consenting MSM were placed on a recall list. This period of the service development was evaluated and results are presented below.

5.3 Aim

The service evaluation aimed to assess the performance of the SMS recall system in recalling MSM who report UAI in the past three months.

The objectives were:

- to determine whether introduction of the SMS reminder was associated with an increase in reattendance among MSM

- to determine whether any change in reattendance was associated with the SMS reminder or with temporal changes (e.g. health promotion introduced at the same time as the intervention).

5.4 **Methods**

5.4.1 Design

A non-randomised controlled design was used. This allowed comparison of a historical and concurrent control group who did not receive SMS reminders with the intervention group who received SMS reminders.

5.4.2 Context and setting

The Mortimer Market Centre (MMC) is a level three sexual health clinic in Camden, central London. It sees approximately 8000 MSM per year for sexual healthcare.

Patients are able to attend for a HIV/STI screen by booking an appointment or 'walking in' to clinic. Clinics are run daily on weekdays, except Wednesday mornings.

5.4.3 Control and intervention groups, time periods

The intervention group consisted of MSM who reported UAI in the past three months, who attended the MMC during the intervention time period and who were listed to receive an SMS reminder to reattend in three months time.

The concurrent control group consisted of MSM reporting UAI in the past three months who attended the service during the implementation of the intervention, but who were not listed to receive the intervention.

The historical control group consisted of MSM reporting UAI in the past three months who attended the service prior to implementation of the intervention. A historical group was used to determine whether any change in reattendance was due to the intervention or due to temporal factors (e.g. health promotion introduced to all MSM at the same time as the intervention).

Each group had a 'visit' period, which was the time of their initial visit, and a reattendance period three to five months later. A reattendance period of three

months was chosen in line with national guidance. An attendance prior to this was considered to be related to the initial episode of care. The reattendance period was considered up to five months after initial visit to allow for reasonable booking delays. These time periods are outlined in table 6.

Table 6: Visit and reattendance time periods for historical and intervention periods

Group	Visit period	Reattendance period
Historical period	1st Sept 2011-31st Nov 2011	1st Dec 2011-1st May 2012
Intervention period	1st Jan 2014- 31st March 2014	1st April 2014- 1st Sept 2014

Control and intervention group definitions

Intervention group: MSM who reported UAI in the past three months, who attended MMC during the intervention time period (1st Jan 2014-31st March 2014) and who were listed to receive an SMS reminder to reattend in three months time

Concurrent control group: MSM who reported UAI in the past three months and who attended MMC during the same time period as the intervention group (1st Jan 2014- 31st March 2014) but who did not consent to receiving an SMS reminder to reattend.

Historical control group: all MSM who reported UAI in the past three months and who attended MMC between 1st September and 31st December 2011, before the active recall strategy was introduced

Reattendance: a return attendance in the follow-up period three to five months after the initial visit**.**

5.4.4   Consent

The project was deemed to be a service evaluation and not requiring ethical approval on review of the Health and Research Authority's document

'Defining Research'(282). SMS reminders were offered to all MSM reporting UAI in the past three months. The service evaluation sought to determine what reattendance rates were being achieved through analysis of routinely collected clinic data. Patients were therefore not consented to be part of the service evaluation.

5.4.5   Outcome measures

Primary outcome:

1. Reattendance rate at three to five months after initial visit

Secondary outcomes:

1. Acceptance rate (proportion of eligible MSM consenting to recall)
2. HIV testing rate

Comparisons of age and HIV testing rates were made between those that reattend compared to non-reattenders.

Baseline age and HIV testing rate of MSM consenting to recall was compared to MSM not consenting to recall to explore whether there were systematic differences between the populations, since receiving the recall reminder was not randomised.

5.4.6   Sample size

Historically, reattendance rates among MSM who report UAI in the past three months and who attend the service has been estimated at 15% using data from the electronic patient records system (unpublished). To detect a 10% increase in reattendance(263, 266) (i.e. 25% reattendance rate) in the intervention period, a sample size of 540 would be required. This assumes that 50% of eligible MSM consent to receiving an SMS reminder, 80% power and 5% α- error.

5.4.7   Statistical methods

Statistical tests used were Chi squared test of proportions or a two-tailed Fisher's exact test where numbers were fewer than five in any one group. Continuous variables, such as age, were transformed into categorical

variables using age groups. Where statistical tests were used, missing variables were excluded from the analysis and the denominator for that group is presented in the results table.

The Mantel-Haenszel method was used to generate a weighted estimate of association between the dichotomous outcome (reattendance) and the dichotomous risk factor (SMS) adjusting for confounders, which were stratified.

Confounding variables that were adjusted for were age and all risk behaviour variables recorded in the clinic electronic patient records. These included reported sexual orientation; history of injection drug use in the past three months; sex with a person from a high-risk area for HIV in the past three months; sex with a partner from West Africa in the past three months; and whether the patient had paid someone or had themselves been paid for sex in the past three months.

5.5 **Results**

5.5.1 **Reattendance rates**

In the intervention period, all eligible patients were required to be consented for recall and all consenting patients were transferred to the recall list.

Of 999 patients eligible for recall, 364 (36%) consented to receiving an SMS reminder, and due to semi-automated transfer to the recall list all received a reminder (figure 9).

Overall, 451/999 (45%) of those attending at baseline reattended for a HIV/STI screen three-five months after SMS reminders were sent out. However there was no difference in reattendance between the group receiving an SMS (163/364: 45%) and the group who did not receive an SMS (288/635: 45%; p=0.861).

In the historical control period, 17.4% (130/745) MSM reattended for a HIV/STI screen three-five months after their initial visit.

The odds ratio of reattendance in the group that consented to recall in the intervention period compared to concurrent controls was 0.98 (95% CI 0.75, 1.27) and in the group that consented to recall in the intervention period compared to the historical controls was 3.84 (95% CI 2.9, 5.08).

Figure 9: Proportions of MSM consenting to recall after semi-automation of the recall system and reattendance rates compared to historical time period
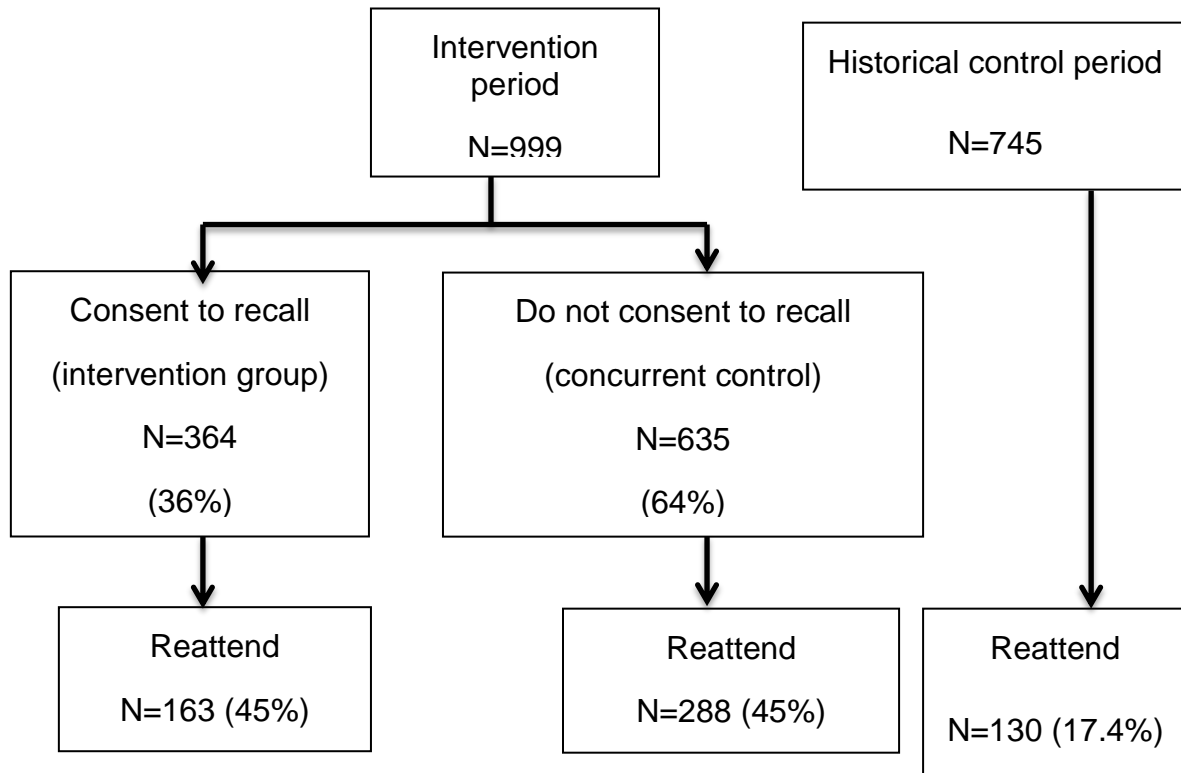
5.5.2 Patient characteristics in the intervention period

5.5.2.1 Reattenders compared to non-reattenders

There was no difference at baseline in key demographics between those that subsequently reattended and those that did not in the intervention period (appendix table 21). Mean age was 35 (range 17-75) among reattenders and 34 (range 16-76; $p=0.080$) among non-reattenders.

The majority had a HIV test at the initial clinic visit (774/947: 81.73%), and this proportion was significantly higher among those who did not reattended compared to those who reattended (451/516: 87.40% vs 323/431: 74.90%; $p<0.001$).

5.5.2.2 MSM consenting to recall compared to MSM not consenting to recall

Almost 1000 MSM were eligible for recall. Median age was 34.7, range 16-76.

MSM consenting to recall were significantly younger than those not consenting to recall (median age 33 years vs 35 years; $p=0.005$). However, this age difference may not be meaningful in practice, as risk behaviours and uptake of interventions are unlikely to differ over a small age difference. Those who consented to recall had a significantly higher rate of HIV testing at baseline (318/364; 91.1%) compared to those who did not consent to recall (456/635; 76.2%; $p<0.001$) (appendix table 22).

5.6 **Discussion**

The results of the service evaluation demonstrate an increase in reattendance rates after introduction of SMS reminders compared to a historical comparison period. However, there was no difference in reattendance between the group that received an SMS reminder and the group that did not during the intervention period. This suggests that the SMS reminder had no effect on reattendance rate. Other factors such as changes in national HIV testing policy recommending three-monthly HIV testing and increased health promotion associated with the offer of a reminder might have contributed to the increase in reattendance rates when comparing historical with intervention periods. These factors combined with changes to the service development over time may have increased reattendance rates to a high baseline level, such that SMS reminders were unable to demonstrate an added benefit in the service evaluation.

Other SMS reminder studies in sexual health clinics(111, 112, 168, 265) and the findings of the systematic literature review in chapter 4 have demonstrated an increase in reattendance rates with SMS reminder. However, a UK study of SMS reminders for a repeat HIV/STI screen for high risk groups including MSM showed no benefit of reminders(260). Their cohort had a high baseline reattendance rate and the addition of the SMS reminder intervention may not have been able to have an additional benefit.

In the service evaluation, those that consented to recall had a higher HIV testing rate at baseline than those that did not consent to recall. This suggests that those who consented to recall might be regular testers (i.e. test as part of routine health maintenance) or highly engaged with sexual health services. It would be useful to determine the frequency of HIV testing among this group from EPR or national surveillance data. Alternatively, the higher HIV testing rate at baseline may be reflective of sexual risk behaviour that influenced the decision to test for HIV.

HIV testing rates at baseline were higher among those that subsequently did not reattend compared to those who reattended. This may be because those

that reattended had recent high-risk sexual exposures within the window period for HIV, meaning that they did not test for HIV at baseline but reattended for a HIV test once they were outside the window period. However, this group may have benefited from recall. It would be useful to determine whether the group that reattended (who had a lower baseline HIV testing rate) were the same as the group that did not consent to recall (who also had a lower baseline HIV testing rate).

Of note, the service development required several modifications to encourage accurate recording of consent to recall and transfer of consenting patient's details to an SMS follow up list.

Using lean principles(283), a number of steps in the patient pathway were identified as potential points of failure. These included the possibility that clinicians were failing to identify that the patient required SMS recall on the follow-up slip and the patient failing to hand the follow-up slip to the clinic receptionist.

To make the pathway more streamlined, a semi-automated system was generated. This extracted data from the patient's risk assessment to determine whether a patient was eligible and had consented to recall. A list of eligible consenting patients was transferred to the clinic administration team to generate an SMS reminder follow up (figure 10).

Figure 10: Patient pathway before semi-automation and after semi-automation of the recall system
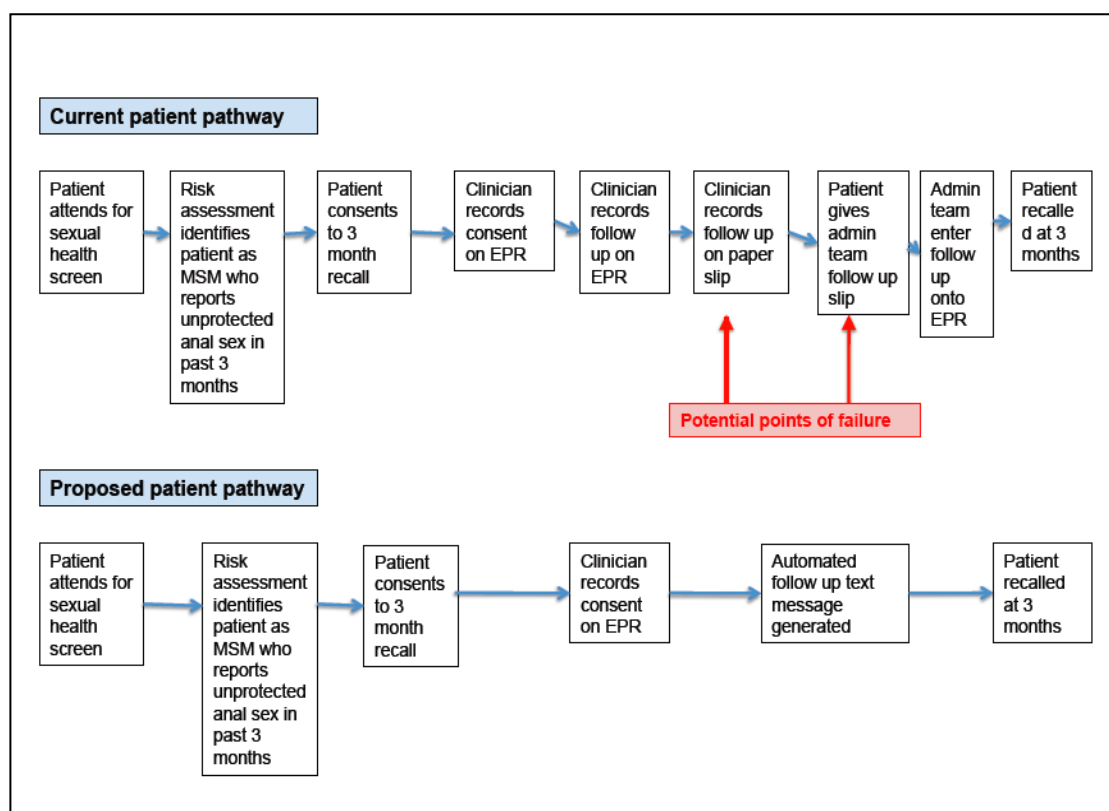
Similar barriers were highlighted in an Australian study by Bourne et al. They acknowledged that their reattendance rate of 40% after introduction of SMS reminders could have been limited by clinicians forgetting to place patients on the SMS list(168).

5.7 Limitations

There were several limitations to this service evaluation. A major limitation was the non-randomised controlled design that was used. This design was used as randomisation was not practical; an SMS recall intervention was already in place for MSM diagnosed with an acute bacterial STI and the service preferred to extend this offer to all MSM instead of using a randomised intervention. Using an observational study design only allows for assessment of 'adequacy' (do the expected changes in outcome occur compared to a previously determined criterion?), as in this study. They can also assess for 'plausibility' (did the intervention have an effect over and

above other external influences?). It does not allow for measure of 'probability' (did the intervention have an effect?), which requires a randomised design to determine whether the difference between intervention and control is due to confounding, bias or chance(284).

Since patients were not randomly allocated to the intervention or control groups, confounders may modify the effect of the intervention. The comparison of the intervention and control groups at baseline suggests that there was no major difference between the groups in terms of age. However, there was a difference between the groups in HIV testing behaviour. The analysis attempted to control for some sexual risk behaviour confounding factors.

Although covariates recorded on the electronic patient record were adjusted for, other factors that were not recorded may have influenced reattendance and been confounders. Examples might include employment status, since access to clinic may have proven to be a barrier for those in work. Sexual risk factors, such as number of partners and recent exposure to HIV may have also influenced reattendance. Some of these factors were therefore explored in the questionnaire survey in the next chapter.

Neither clinician nor patient was blinded to the intervention, as clinicians offered the SMS intervention to patients in clinic. Therefore, the intervention was subject to selection bias. Clinicians may have offered the SMS intervention to those MSM that they perceived to be at highest risk for HIV and STIs, or who they perceived to be unlikely to reattend (and hence benefit from the intervention). This may have influenced the true reattendance rate in response to the intervention, The intervention relied on clinicians asking patients for consent. Clinicians may have stated that a patient did not consent to recall if they did not ask for consent. Participants may have received more health promotion from health professionals who offered them the SMS intervention. Only those with high perceived sexual risk may have accepted the SMS intervention.

A low proportion of eligible patients accepted an SMS reminder (36%). However, this uptake rate was similar to that seen in other studies offering

SMS reminders for STI screening(168). Reasons for low uptake of the reminder may have been clinician/service related barriers: clinicians may not have appropriately identified eligible patients, may not have consented eligible patients, or may not have recorded consent. Patient related barriers may have included low risk perception among eligible patients resulting in not consenting to receiving a reminder. Intervention related barriers include reminders not being acceptable to patients in the form or at the time interval offered. A process evaluation would have been useful to identify clinician/service-related barriers. The survey aimed to explore patient and intervention-related barriers.

The intervention required several modifications. This was accompanied by clinician education and awareness raising. The influence of health promotion regarding frequent testing over the time horizon of the service development might have confounded results. Furthermore, external factors such as national policy recommending three-monthly testing and HIV testing campaigns would have reinforced health promotion advice.

Reattendance may also have been prompted by another reason, such as symptoms or high-risk exposure. Therefore, reattendance rates cannot be wholly attributed to the intervention.

Furthermore, there is some movement of patients, particularly those who are HIV negative or of unknown HIV status, between central London clinics, but the extent of this is unknown. National and local surveillance is unable to capture this information(285). Therefore, some patients may have reattended at another clinic. However, this would not have been captured in the service evaluation as it utilised local clinic based electronic patient records.

In this study, a smaller proportion of MSM consented to receiving an SMS reminder than anticipated. The 36% of eligible men who consented to receiving an SMS reminder was lower than the 50% consent rate estimated in the sample size calculation. However, the large population in the service evaluation means that the analysis was not underpowered. The consent rate achieved is also lower than the 80% of patients who consented to recall offer in a similar intervention in the same clinic to actively recall MSM with an acute

bacterial STI(77). However that group may have had increased motivation to reattend/retest as they were symptomatic. A recall initiative in another London clinic found that SMS was offered to almost 50% of eligible patients with 10% of those offered recall declining to be added to the recall list(260).

The results from this evaluation may not be generalisable to other clinics as the intervention was only conducted in a single central London clinic. The eligible MSM population was already exposed to SMS reminders for other indications (e.g. PEPSE). The impact of SMS reminders in increasing reattendance rates for MSM reporting UAI may therefore be diminished in this sensitised population.

Finally, the three-month recall for this reminder system was chosen based on national guidelines for testing for HIV for MSM who report UAI with a new partner(1). However, there are no data available on the acceptability of SMS reminders for HIV/STI testing among MSM and the drivers and barriers to testing when receiving a reminder.

5.8 Conclusion

The service evaluation suggests that SMS reminders were not associated with an increase in reattendance rates for HIV/STI screening among MSM who reported UAI in the past three months. However, there was an overall increase in reattendance rates after the introduction of SMS reminders compared to a historical time period. It is not possible to determine whether this increase was due to the SMS reminders or confounded by health promotion activities that might have increased reattendance/re-testing rate regardless of exposure to the SMS reminder.

The possible failure of SMS reminders to increase reattendance/re-testing rates may have been due to several reasons. These include participant factors (e.g. low perceived sexual risk), intervention factors (e.g. the SMS message not being appropriate, inappropriate time interval between the initial visit and the SMS) or contextual factors (e.g. a change in socio-cultural testing norms due to policy or health promotion changes).

The next stage in the project explored these issues through a questionnaire survey and in-depth interviews.

Chapter 6   Study 2: Questionnaire survey

6.1 Introduction

Chapter 5 presented results of an evaluation of the service development in which SMS reminders were introduced in clinic to remind men who have sex with men (MSM) at high risk of HIV infection to return for a HIV/STI screen. Although there was an increase in reattendance rates compared to baseline, this increase may not have been due to the SMS reminder. To explore patient level drivers and barriers to returning when sent a reminder, a short self-completion questionnaire survey was delivered in clinic.

The rationale for the survey was the need to explore which factors and attitudes were associated with intention to return for a HIV/STI screen if sent a reminder. The results of such a survey could be used to target a recall system or provide additional behavioural interventions to those who are identified as not intending to return for a HIV/STI screen if sent a reminder. The specific aims are outlined in the next section.

Participants who completed a questionnaire and received an active recall reminder were followed to see if they returned for a HIV/STI screen in the next three to five months at the same clinic. This reattendance time period was chosen as national guidance is to recommend retesting of MSM at high risk of HIV/STIs every three months. The period chosen allowed retesting within up to five months to account for reasonable delays in booking appointments. Reattendance at less than three months was considered to be within the same episode of care as the initial presentation. Therefore, the study also explored whether intention to reattend was associated with documented reattendance among those who received an SMS active recall reminder within this timeframe, and which attitudes were associated with documented reattendance.

6.2 **Aim**

The main aim of the survey was to explore what factors encourage or discourage HIV-negative MSM to engage with an active recall programme. It also explored what are the preferred modes and frequency of active recall for HIV and STI testing.

Specific objectives were:

1. To determine which demographic and sexual risk factors (HIV/STI testing history, sexual risk behaviour and sexual health) were associated with intention to reattend if sent an active recall reminder
2. To determine which attitudes to testing and reminders were associated with intention to reattend if sent an active recall reminder
3. To determine which type and interval of recall is preferred by survey respondents
4. To determine the documented reattendance rate among survey respondents after receipt of a SMS reminder
5. To determine which attitudes to testing and reminders were associated with documented reattendance among survey respondents after receipt of an SMS reminder

6.3 **Methods**

6.3.1 Study design

The study was a cross-sectional survey and longitudinal observational cohort analysis of MSM attending the Mortimer Market Clinic between 1st April-1st July 2014.

6.3.2 Survey instrument

The survey was a pen and paper self-completion questionnaire, designed to take less than 10 minutes to complete (appendix 4.3 for survey instrument). Clinic ID and date of birth were recorded on the survey to allow linkage to clinical and attendance information.

It covered four topic areas:

1. Demographics
2. Sexual health: HIV and STI testing history, STI infection history
3. Sexual risk behaviour
4. Attitudes to active recall for HIV and STI testing including
   a. Preferred frequency of HIV and STI testing recall
   b. Preferred place of HIV and STI testing recall
   c. Reminder preference for HIV and STI testing

The questions in the survey were informed by the Theory of Planned Behaviour (TPB) (see chapter 2): behavioural attitudes, subjective norms, perceived behavioural control and behavioural intention of reattendance. Questions that explored the TPB constructs are identified in the appendix (appendix 4.4). Actual behaviour was elicited from clinical records, by capturing reattendance data. As far as possible, these questions were designed using the construct recommended by Ajzen(147), and taken from validated surveys on sexual health (appendix 4.4). Where no validated questions were available, questions were based on published evidence.

The survey was pretested using expert review and cognitive interview.

6.3.3 Cognitive interviews

Expert review and eight cognitive interviews were conducted to test the questionnaire survey for understanding and construct validity prior to roll out. The cognitive interviews explored participants' understanding of the questions in the survey tool in comparison with the stated objective for each of the survey questions (appendix 3.3).

Participants were provided with a patient information sheet (appendix 3.1) and a convenient time was arranged for the interview. Participants were consented prior to the interview (appendix 3.2). Each interview lasted 45-50 minutes, was audio-recorded and participants were reimbursed for reasonable travel costs and given a small high street voucher for their participation. Participants were encouraged and trained to use the 'think aloud' technique using a standard technique in which they are asked to count the number of windows in their home(186). However, respondent debriefing was used where participants were unable to perform the 'think aloud' technique.

The audio recording and interview notes were reviewed immediately after each interview. Data were then analysed using a coding frame for each participant and for each question in the survey using the following headings: objective/question mismatch, item specific issues (cognition, recall, judgement, response, logic, culturally oriented defects), ordering issues, overall length issues and visual layout issues. The coding frame was adapted from a National Centre for Social Research template that is based on framework charting(207). For each question, an item summary was presented by synthesising common themes across participants' answers. Findings were used to generate the final version of the survey tool. The survey tool was not retested.

As a result of the cognitive interviews, several changes were made to the layout of the tool to make it more 'user-friendly'. Some questions were identified as difficult to understand, were misinterpreted, were excessively long, or had multi-item answer options which were difficult to answer. These questions were modified to improve comprehension, judgment and facilitate recall. Details of the cognitive interviews and changes made to the survey tool are presented in the appendix (appendix 3.3).

6.3.4 Survey sampling

Participants for the questionnaire survey were recruited from the sexual health clinic during routine sexual health consultations. All participants had access to a member of the research team for further discussion regarding the study if needed.

Participants did not receive any payment.

6.3.4.1 Inclusion criteria

- Men who report having sex with men attending the study clinic
- Aged 16 and above
- Able to read and write in English
- HIV negative

6.3.4.2 Exclusion criteria

MSM diagnosed with HIV, MSM receiving post exposure prophylaxis for

sexual exposure (PEPSE) and MSM in the PROUD study of pre-exposure prophylaxis were excluded from the survey as they are actively recalled as part of routine clinic practice.

For the cognitive interviews, MSM who declined recording of the interview, or had insufficient spoken English were excluded.

6.3.5   Sample size

To enable both the precision estimate and provide power to detect the association described below, an overall sample size of 323 MSM was required. Assuming a response rate of 30% then 1067 MSM would need to be invited to participate. Further details of the sample size calculation are provided in the appendix (appendix 4.2).

The survey needed to be completed by 320 MSM to provide 10% precision around the estimate that 50% of MSM completing the survey would state that they intended to reattend for an HIV/STI test if they receive a reminder. This proportion was chosen since it represents the 'worst case scenario' for precision and similar surveys had not estimated intention to reattend.

The survey needed to be completed by 323 MSM to provide 80% power and 5% alpha to demonstrate an association between reporting UAI with a CMP and intention to reattend if the odds ratio for this association is two. This assumed that 33% of respondents would report UAI with a CMP in the past three months (72). It also assumed that 50% of MSM who report no UAI in the past three months would intend to reattend.

6.3.6   Consent and confidentiality

The study was reviewed favourably by the Leeds West Ethics Committee (REC reference13/YH/0347, appendix 4.1). Written informed consent for the questionnaire study was obtained by providing a brief explanation at the beginning of the questionnaire with instructions to tick a box to confirm that they had read and understood the information provided before proceeding.

6.3.7 Statistical analysis

Simple descriptive analysis and comparative analysis, using Chi squared test of proportions was performed using the statistical package Stata 10.1. Where numbers were fewer than five in any one group a two-tailed Fisher's exact test was used. Continuous variables were assessed for normality of distribution. Where distribution was not normal, a non-parametric test, such as the Mann-Whitney U test, was used.

The analysis compared MSM who intended to reattend for HIV/STI screen if they received an active recall reminder, compared to MSM who did not intend to reattend.

Responses to attitudinal questions were grouped by agreement with the attitude (i.e. 'undecided' responses were grouped with disagreeing with the statement) as the analysis aimed to test whether agreement with the attitude was associated with outcome. Furthermore, cognitive interviews suggested that there was little difference between the categories that were collapsed into a dichotomous outcome. Reliability was determined using Cronbach's alpha. Pearson's correlation was used to test for correlation between statements.

Finally logistic regression analysis was used to estimate the effect of the explanatory variables on intention to reattend. A binary logistic regression model was used in which the outcome- intention to reattend- was reduced to a binary outcome. Although intention to reattend was asked in a four point Likert scale, there was little spread across the categories. Furthermore, the cognitive interviews suggested that there was little difference between the categories that were collapsed into a dichotomous outcome. Interaction was not tested as the outcome of 'not intending' to reattend was rare.

Explanatory variables were selected based on the literature and plausibility. Univariable analysis was used to determine which explanatory variables were associated with the outcome with $p<0.200$. These variables were included in the multivariable regression models. A backwards step-wise regression approach was used to develop a parsimonious model. Explanatory factors were not grouped before fitting them into the model to allow all included

133

factors to be treated equally. Only results of variables included in the parsimonious model are presented in the multivariable regression analysis.

Questions with low discriminatory power; with high correlations of 0.9 or greater; or which did not contribute to explaining variance in the data were excluded.

Fit of the final binary model was tested by calculating sensitivity and specificity of the model and plotting a Receiver Operating Characteristic curve (ROC).

Regression analyses were also performed to test whether any of the attitudinal responses was associated with documented reattendance among survey respondents who received an SMS reminder in a binary logistic regression model, adjusting for key demographics and UAI with CMP.

6.4 **Results**

This section describes the response rate, participant characteristics and addresses the objectives outlined in section 6.2 which is split into four sections.

1. Descriptive analysis
    a. Association of demographic characteristics and reason for returning to clinic with intention to reattend
    b. Association of testing history and sexual health with intention to reattend
    c. Association of sexual risk behaviour with intention to reattend
    d. Attitudes associated with intention to reattend
    e. Preferred type and frequency of recall
2. Binary regression analysis of factors associated with intention to reattend
3. Documented reattendance rate among SMS recipients
4. Attitudes associated with documented reattendance of SMS recipients

In the descriptive analysis, the distribution of the explanatory variable in the survey population is described. This is presented in tables with column

percentages. The association between intention to reattend and each explanatory variable is then made and results are presented in tables with row percentage. This univariate association is explored using chi-squared test (or Fisher's exact test).

Results of the univariable and multivariable binary regression analysis is only presented for covariates that were associated with the outcome with p<0.200. Detailed results are presented in the appendix (appendix 4.5).

6.4.1   Response rate and reason for attendance

During the survey period, 1067 MSM attended the service and were offered the survey. The survey was offered to all men attending the service by administrative staff at clinic reception. A member of the research team was available in case of any questions, but did not directly offer the survey or consent survey participants.

The survey was completed by 406 MSM who were eligible to take part in the study. The response rate was therefore 38%. Characteristics of survey respondents and non-respondents were not directly compared as ethics approval was not requested to obtain information about non-respondents from the electronic patient records database.

More than three quarters of survey respondents (319/395; 81%) were not prompted to attend clinic by a reminder (appendix table 23). Eighteen percent (75/395) of respondents were attending clinic due to a reminder such as an SMS or a verbal clinical reminder at their previous clinic visit.

6.4.2   Participant characteristics

Participant characteristics are summarised in table 7. The median age of respondents was 34 (range 19-71). Respondents were slightly older than MSM attending genitourinary medicine (GUM) clinics in England with 45% of the survey population aged 35 and over, compared to 40% of MSM attending GUM clinics in England in 2013 (appendix table 24).

The majority of participants were of white ethnicity (326/394; 83%). This is comparable to the ethnicity of MSM attending GUM clinics in England in 2013; in 2013 80% of MSM identified as 'white' ethnicity. Just under half (190/395;

48%) were born outside the UK. This is higher than that seen among MSM attending GUM clinics in England where approximately a quarter of attendees in 2013 were born outside the UK(286) (appendix table 24).

Over half of respondents were employed full-time (243/393: 62%). This is lower than the UK population in which the employment rate in 2013 was 71.4%(287).

A large proportion of respondents have completed a university degree or higher (278/395: 70%). This is higher than reported in the 2010 National Survey of Attitudes and Lifestyle in which 37% of MSM reported a university degree or higher(288). In the 2011 Census, 28% of men had completed a university degree or above(289), suggesting that the survey respondents were a more highly educated group compared to the general UK population.

Table 7: Survey participant characteristics

Participant characteristic	Number (%) (N= 395[1])
Age	Median 34 Range 19-71
Ethnicity	
White	326 (83%)
Black (African/Caribbean/Other)	17 (4%)
South East Asian	8 (2%)
Asian (Indian/Pakistani/Bengali)	8 (2%)
Mixed/Other	35 (9%)
Missing[2]	12
Born in UK	
Yes	205 (52%)
No	190 (48%)
Missing	11
Occupation	
Employed full-time	243 (62%)
Employed part-time	14 (4%)
Self-employed	67 (17%)
Unemployed	9 (2%)
Student	40 (10%)
Retired	11 (3%)
Long-term sick/medically retired	1 (0.2%)
Other	8 (2%)
Missing	13
Education	
In full/part-time education	30 (8%)
O Levels/GCSEs	24 (6%)
A-levels	46 (12%)
Finished education with no qualifications	7 (2%)
University degree or above	278 (70%)
Other	10 (2%)
Missing	11

---

[1] Number (N) is the maximum number of respondents answering a question. The exact number of participants answering the question can be calculated using the column total for each question.

[2] Missing values are not included in the column percentages

6.4.3 Association of demographic characteristics and reason for returning to clinic with intention to reattend

The main focus of the survey was to explore the factors associated with intention to reattend. The vast majority of participants (356/382; 93%) stated that they intended to reattend if sent a reminder.

There was an association between whether returning to clinic was prompted by a reminder or not and intention to reattend (p=0.012) (appendix table 23).

Age was associated with intention to reattend (p=0.001) (table 8). Intention to reattend was greater among younger age groups. Ethnicity (p=0.915), being born in the UK (p=0.150), occupation (p=0.560) and education (p=0.181) were not associated with intention to reattend.

Table 8: Demographics characteristics of survey respondents and association with intention to reattend if sent a reminder

	Distribution in survey sample (N= 397[3]) *Column percentage*	Intending to reattend if sent a reminder (N=361[3]) *Row percentage*	Association of sexual health variable with intention to reattend: P value[4]
Age			**0.001[#]**
18-25	42 (14%)	41 (100%)	
26-30	78 (26%)	71 (93%)	
31-35	46 (15%)	44 (100%)	
36-40	46 (15%)	45 (98%)	
41-45	31 (10%)	29 (94%)	
46-50	27 (9%)	21 (88%)	
>50	29 (10%)	25 (86%)	
Missing	107	85	
Ethnicity			0.915
White	326 (83%)	295 (94%)	
Black (African/Caribbean/Other)	17 (4%)	15 (94%)	
South East Asian	8 (2%)	7 (88%)	
Asian (Indian/Pakistani/Bengali)	8 (2%)	7 (88%)	
Mixed/Other	35 (9%)	31 (91%)	
Missing	12		
Born in UK			0.150
Yes	205 (52%)	180 (91%)	
No	190 (48%)	176 (96%)	
Missing	11	5	
Occupation			0.560
Employed full-time	243 (62%)	218 (93%)	
Employed part-time	14 (4%)	12 (86%)	
Self-employed	67 (17%)	61 (95%)	
Unemployed	9 (2%)	8 (100%)	
Student	40 (10%)	38 (97%)	
Retired	11 (3%)	9 (82%)	
Long-term sick/medically retired	1 (0.2%)	1 (100%)	

---

[3] Number (N) is the maximum number of respondents answering a question. The exact number of participants answering the question can be calculated using the column total for each question.
[4] Fisher's exact where cells contain <5 observations. Chi2 test where >=5 observations
[#] statistically significant, p<0.05

Other	8 (2%)	7 (88%)	
Missing	13	14	
Education			0.181
In full/part-time education	30 (8%)	30 (100%)	
O Levels/GCSEs	24 (6%)	23 (100%)	
A-levels	46 (12%)	43 (96%)	
Finished education with no	7 (2%)	5 (83%)	
qualifications	278 (70%)	246 (91%)	
University degree or above	10 (2%)	9 (100%)	
Other	11	14	
Missing			
Sexuality			**0.015**[#]
Heterosexual/straight	4 (1%)	3 (75%)	
Gay	351 (88%)	321 (95%)	
Bisexual	36 (9%)	31 (86%)	
Other	6 (2%)	4 (67%)	
Missing	9	6	

6.4.4   Association of testing history and sexual health with intention to reattend

Testing history and sexual health were explored to determine whether past behaviour is associated with future intention to attend for a HIV/STI screen. The survey population was a clinic attending population, and the majority had a HIV (80%) or STI screen (72%) test in the past 12 months. Respondents had a median of two HIV tests in the past 12 months; however the range was wide (1-21). The commonest STI diagnosed in the past 12 months was gonorrhea (19%).

Past testing behavior was associated with future intention to test (table 9). Time since last STI screen was significantly associated with intention to reattend (p=0.005). Intention to reattend was highest amongst those who had a HIV screen in the last 12 months or 1-2 years ago or never screened but lower in those who last had a screen more than two years previously.

However, there was no association of having a HIV test on the day of the survey (p=0.103), time since last HIV test (p=0.257), having a STI screen on the day of the survey (p=0.120) or having a history of STIs with intention to reattend.

Table 9: Sexual health of survey respondents and association with intention to reattend if sent a reminder

	Distribution in survey sample (N= 406[5]) *Column percentage*	Intending to reattend if sent a reminder (N=361[3]) *Row percentage*	Association of sexual health variable with intention to reattend: P value[6]
SEXUAL HEALTH			
Having a HIV test today			
Yes	262 (66%)	237 (94%)	0.103
No	86 (22%)	73 (88%)	
Don't know yet	47 (12%)	43 (96%)	
Missing[7]	11	8	
Ever had an HIV test before			
Yes, in last 12 months	315 (80%)	281 (93%)	0.257
Yes 1-2 years ago	49 (12%)	47 (98%)	
Yes >2 years ago	18 (5%)	16 (89%)	
No	13 (3%)	10 (83%)	
Missing	11	7	
If tested in the past 12 months, number of HIV tests	Median: 2 Range 1-21	Median 2 Range 1-6	0.943
Where did you go for your last HIV test?			
A different NHS sexual health clinic	51 (13%)	46 (92%)	0.894
A+E	1 (0.3%)	1 (100%)	
GP	6 (1.5%)	6 (100%)	
This sexual health clinic	277 (73%)	249 (93%)	
Private clinic	11 (3%)	10 (100%)	
Rapid test centre	6 (1.6%)	6 (100%)	
Home sampling kit	6 (1.6%)	6 (100%)	
Other	21 (5%)	18 (90%)	
Missing	27	37	
Having an STI test today			
Yes	255 (65%)	233 (95%)	0.120
No	84 (21%)	72 (90%)	

---

[5] Number (N) is the maximum number of respondents answering a question. The exact number of participants answering the question can be calculated using the column total for each question.
[6] Fisher's exact where cells contain <5 observations. Chi2 test where >=5 observations
[7] Missing values are not included in the column percentages

Don't know yet		55 (14%)	48 (89%)	
Missing		12	8	
Ever had an STI test before				**0.005#**
Yes, in last 12 months		282 (72%)	253 (93%)	
Yes 1-2 years ago		54 (14%)	53 (100%)	
Yes >2 years ago		37 (9%)	29 (81%)	
No		20 (5%)	17 (94%)	
Missing		13	9	
If tested in the past 12 months, number of STI tests		Median 2 Range 1-9	Median 2 Range 1-6	0.575
STIs diagnosed in past 12 months[8]				
Syphilis	Yes	16 (4%)	16 (100%)	0.273
	No	390	345 (93%)	
HCV	Yes	1 (0.2%)	1 (100%)	0.788
	No	405	360 (93%)	
Gonorrhoea	Yes	79 (19%)	73 (97%)	0.119
	No	327	288 (92%)	
LGV	Yes	0 (0%)	0 (0%)	n/a
	No	406	361 (93%)	
Chlamydia	Yes	60 (15%)	52 (90%)	0.231
	No	346	309 (94%)	
HBV	Yes	2 (0.5%)	2 (100%)	0.704
	No	404	359 (93%)	
Can't remember the name	Yes	8 (2%)	7 (100%)	0.474
	No	398	354 (93%)	
Never had an STI	Yes	103 (25%)	92 (92%)	0.552
	No	303	269 (94%)	
Other	Yes	65 (16%)	56 (89%)	0.128
	No	341	305 (94%)	

[8] Participants were asked to tick STIs diagnosed in the past 12 months. It is assumed that they were not diagnosed with the STI in question if they did not tick the corresponding box for that STI.
statistically significant, p<0.05

6.4.5 Association of sexual risk behaviour with intention to reattend

Sexual risk behaviour was explored in the survey to determine whether it influenced intention to test for HIV/STIs. The vast majority of respondents reported having ever had anal sex with a man (94%). Half reported having a regular male partner (RMP). Three quarters knew their RMP's HIV status to be HIV negative and 16% had a HIV positive partner. Just over half reported UAI with their RMP in the past three months

A smaller proportion (36%) reported UAI with a casual male partner (CMP) in the past three months. A large proportion of both MSM reporting UAI with a CMP in the past three months (125/132: 94.7%) and those reporting no UAI with a CMP in the past three months (205/230: 89.1%) intended to reattend. The odds ratio of MSM who report UAI with a CMP intending to reattend compared to MSM who report no UAI with a CMP was 2.18 (95% CI 0.91,5.18; p=0.693).

Respondents had a median of 10 different CMP in the past three months (range 1-22). Respondents had receptive anal sex with a median of one CMP in the past three months (range 0-10).

Certain high-risk sexual behaviours were also associated with intention to reattend. Among respondents who reported the highest risk behaviour (receptive UAI with a CMP in the past three months), there was an association between number of partners of unknown status and intention to reattend (p=0.040) (table 10).

However, there was no association of history of anal sex (p=0.495), having a regular male partner (RMP) (p=0.526), serostatus of the RMP (p=0.154) or having UAI with the RMP (p=0.233) with intention to reattend.

Table 10: Sexual risk behaviour of survey respondents and association with intention to reattend if sent a reminder

	Distribution in survey sample (N= 393[9]) *Column percentage*	Intending to reattend if sent a reminder (N=361[7]) *Row percentage*	Association of sexual risk behaviour variable with intention to reattend: P value[10]
SEXUAL LIFESTYLE			
Ever had anal sex with man			
Yes	368 (94%)	329 (93%)	0.495
No	25 (6%)	23 (96%)	
Missing	13	9	
REGULAR MALE PARTNER	**N= 183[7]**	**N=164[7]**	
Has RMP (N=368)			
Yes	183 (50%)	164 (94%)	0.526
No	182 (50%)	163 (92%)	
Missing	3	34	
Time with RMP	Median 43.5 months Range: 0.5-444 months	Median 43.5 months	0.731
RMP HIV status			
Known and HIV positive	29 (16%)	28 (100%)	0.154
Known and HIV negative	135 (75%)	124 (93%)	
Do not know status	15 (8%)	11 (85%)	
Missing	4	1	
UAI with RMP in past 3 months			
Yes	98 (54%)	90 (96%)	0.233
No	82 (46%)	74 (91%)	
Missing	3	0	
Sexual position when UAI with RMP in past 3 months			
Always top	20 (21%)	19 (100%)	0.386

---

[9] Number (N) is the maximum number of respondents answering a question. The exact number of participants answering the question can be calculated using the column total for each question.
[10] Fisher's exact where cells contain <5 observations. Chi2 test where >=5 observations

Mostly top	13 (13%)	12 (100%)	
Always bottom	15 (16%)	12 (86%)	
Mostly bottom	14 (15%)	14 (100%)	
Versatile	34 (35%)	31 (94%)	
Missing	2	2	
CASUAL MALE PARTNER	**N= 368[7]**	**N=361[7]**	
Number of different CMP in past 3 months	Median 10 Range 1-22	Median 10 Range 2-20	0.077
UAI with CMP in past 3 months Yes No Missing	132 (36%) 230 (62%) 6	125 (94%) 205 (92%) 6	0.693
Sexual position when UAI with CMP in past 3 months Always top Mostly top Always bottom Mostly bottom Versatile Missing	43 (33%) 21 (16%) 23 (18%) 16 (12%) 27 (21%) 2	41 (93%) 20 (95%) 20 (95%) 15 (88%) 27 (96%) 2	0.909
Receptive UAI with CMP Number in past 3 months Of these:	Median 1 (range 0-10)	Median 1 (range 0-10)	0.267
Number known to be HIV positive	No observations	No observations	n/a
Number known to be HIV negative	Median 1 (range 1-7)	Median 1 (range 1-7)	0.743
Did not know status	Median 1 (range 0-10)	Median 1 (range 0-7)	**0.040[#]**

6.4.6 Attitudes associated with intention to reattend

The main focus of the survey was to explore attitudes to HIV/STI testing and reminders and their association with intention to reattend for a HIV/STI screen. Respondents were asked about their agreement with national HIV testing guidelines which recommends annual testing, and the majority agreed with this guidance (84%) (table 11).

When considering attitudes for regular HIV testing, over one third of respondents believed that they were at risk of becoming infected with HIV (37%), 63% did not want to put others at risk and half had gay friends who tested for HIV. However, 22% felt that fear of a positive HIV test put them off testing (table 11).

Certain attitudes to testing were associated with intention to reattend in univariate analysis. For example having gay friends who test for HIV regularly was associated with intention to reattend (p=0.050), as was agreement with national HIV testing guidelines (p<0.001) (table 11).

The majority of participants had positive attitudes to reminders. Over three quarters (77%) liked being reminded to check health status (table 12), a small proportion (22%) were concerned about the confidentiality of reminders or being stigmatised by receiving a reminder (15%). Over half (56%) felt that receiving a reminder to retest would increase their likelihood of testing.

Liking being reminded to check health status (p<0.001) was associated with intention to reattend. In contrast, being concerned about the confidentiality of reminders (p<0.001) and being concerned about being stigmatised by receiving a reminder (p<0.001) was associated with not intending to reattend (table 12).

There was no association between believing that you were at risk of HIV (p=0.567), fear of a positive HIV test (p=0.304), not wanting to put others at risk (p=0.349) and intention to reattend (table 12).

Although the majority of respondents preferred to test at an NHS GUM clinic (table 13), there was no association between preferred venue for testing and

intention to reattend. Confidentiality of service, proximity of clinic, same day results and shorter waiting times were the most important factors when deciding where to have a regular test for HIV/STIs, but this was not associated with intention to reattend.

6.4.7   Preferred type and frequency of recall

SMS was the preferred mode of reminder for three quarters of respondents (304/406; 75%) and was associated with intention to reattend ($p<0.001$) (table 12).

Although home sampling may influence access to testing, there was no association between preference for home sampling or clinician testing and intention to reattend ($p=0.130$) (table 13).

The preferred testing frequency was every three months (41%) followed by every six months (31%) (table 11). Those intending to reattend preferred more frequent reminders ($p<0.001$), with the majority preferring a reminder every three or six months. Those not intending to reattend were most likely to not want a reminder (table 12).

Table 11: Views of survey respondents on HIV/STI testing frequency and association with intention to reattend if sent a reminder

	Distribution in survey sample (N= 406[11]) *Column percentage*	Intending to reattend if sent a reminder (N=361[11]) *Row percentage*	Association of testing frequency variable with intention to reattend: P value[12]
HIV AND STI TESTING FREQUENCY			
Agreement with national HIV testing guidelines (12 months testing)			
Agree (strongly/tend to)	337 (84%)	304 (94%)	0.236
Disagree (strongly/tend to/undecided)	62 (16%)	54 (90%)	
Missing[13]	7	3	
Test as often as would like to			
Yes	292 (74%)	259 (93%)	0.989
No	105 (26%)	96 (93%)	
Missing	9	6	
Preferred frequency of testing (can pick more than one option)[14]			
Every month Yes	16 (4%)	15 (94%)	0.939
No	390	346 (93%)	
Every 3 months Yes	165 (41%)	149 (95%)	0.292
No	241	212 (92%)	
Every 6 months Yes	125 (31%)	115 (95%)	0.351
No	281	246 (92%)	
Every 12 months Yes	76 (19%)	69 (95%)	0.639
No	330	292 (93%)	
After every new partner Yes	35 (9%)	31 (89%)	0.243
No	371	330 (94%)	
Other Yes	16 (4%)	12 (80%)	**0.036[#]**
No	390	349 (94%)	
Attitudes to regular HIV testing *Believe at risk of becoming infected*			

---

[11] Number (N) is the maximum number of respondents answering a question. The exact number of participants answering the question can be calculated using the column total for each question.

[12] Fisher's exact where cells contain <5 observations. Chi2 test where >=5 observations

[13] Missing values are not included in the column percentages

[14] Participants were asked to tick all preferred frequencies of testing. They were able to pick more than one answer. It is assumed that if they did not tick an answer, they did not prefer that option.

[#] statistically significant, p<0.05

with HIV			
Agree (strongly/tend to)	146 (37%)	131 (92%)	0.567
Disagree (strongly/tend to/undecided)	252 (64%)	226 (94%)	
Missing	8	4	
Fear of positive tests puts me off testing			
Agree (strongly/tend to)	89 (22%)	78 (91%)	0.304
Disagree (strongly/tend to/undecided)	306 (78%)	276 (94%)	
Missing	11	7	
Don't want to put others at risk			
Agree (strongly/tend to)	222 (63%)	345 (93%)	0.349
Disagree (strongly/tend to/undecided)	8 (50%)	14 (87%)	
Missing	5	2	
Most gay friends test for HIV regularly			
Agree (strongly/tend to)	118 (52%)	186 (96%)	**0.050**[#]
Disagree (strongly/tend to/undecided)	175 (48%)	170 (91%)	
Missing	9	5	

Table 12: Views of survey respondents on HIV/STI testing reminders and association with intention to reattend if sent a reminder

		Distribution in survey sample (N= 406[15]) *Column percentage*	Intending to reattend if sent a reminder (N=361[14]) *Row percentage*	Association of testing reminder variable with intention to reattend: P value[16]
TESTING REMINDERS FOR HIV/STIs				
Reminder preference (can pick more than one option)[17]				
SMS	Yes	304 (75%)	294 (98%)	**<0.001[#]**
	No	102	67 (77%)	
Phone call	Yes	19 (5%)	16 (89%)	0.446
	No	387	345 (93%)	
Letter	Yes	25 (6%)	25 (100%)	0.165
	No	381	336 (93%)	
Email	Yes	100 (25%)	97 (98%)	**0.030[#]**
	No	306	264 (92%)	
Home sampling	Yes	28 (7%)	25 (89%)	0.381
	No	378	336 (94%)	
Don't want a reminder	Yes	37 (9%)	19 (56%)	**<0.001[#]**
	No	369	342 (97%)	
Other	Yes	3 (0.7%)	2 (100%)	0.870
	No	403	359 (93%)	
Attitudes to testing reminders *Like being reminded to check health status*				
Agree (strongly/tend to)		303 (77%)	295 (99%)	**<0.001[#]**
Disagree (strongly/tend to/undecided)		89 (23%)	63 (72%)	
Missing		13	3	
Concerned about confidentiality of reminders				

15 Number (N) is the maximum number of respondents answering a question. The exact number of participants answering the question can be calculated using the column total for each question.
16 Fisher's exact where cells contain <5 observations. Chi2 test where >=5 observations
17 Participants were asked to tick all preferred reminder. They were able to pick more than one answer. It is assumed that if they did not tick an answer, they did not prefer that option.
statistically significant, p<0.05

Agree (strongly/tend to)	84 (22%)	70 (85%)	**0.001#**	
Disagree (strongly/tend to/undecided)	308 (78%)	288 (95%)		
Missing	13	3		
Concerned about being stigmatised for receiving a reminder				
Agree (strongly/tend to)	58 (15%)	46 (81%)	**<0.001#**	
Disagree (strongly/tend to/undecided)	329 (85%)	308 (95%)		
Missing	18	7		
Preferred reminder frequency (can pick more than one option)				
Every 3 months	125 (31%)	123 (100%)	**<0.001#**	
Every 6 months	142 (35%)	139 (99%)		
Once a year	76 (19%)	72 (95%)		
Don't' want a reminder	35 (9%)	15 (45%)		
Other	10 (2%)	8 (89%)		
Factors that would increase likelihood of testing (can pick more than one option)[18]				
Reminder to test	Yes	226 (56%)	222 (99%)	**<0.001#**
	No	180	139 (85%)	
Recent UAI with CMP	Yes	264 (65%)	236 (91%)	**0.044#**
	No	142	125 (97%)	
Home sampling kit given at clinic visit for future use	Yes	85 (21%)	75 (90%)	0.231
	No	321	286 (94%)	
Home sampling kit sent in post				
	Yes	116 (29%)	110 (95%)	0.427
	No	290	251 (93%)	
Other	Yes	16 (4%)	12 (75%	**0.017#**
	No	390	349 (94%)	

---

18 Participants were asked to tick all factors that would increase likelihood of testing They were able to pick more than one answer. It is assumed that if they did not tick an answer, they did not prefer that option.
statistically significant, p<0.05

Table 13: Views of survey respondents on HIV/STI testing reminders and association with intention to reattend if sent a reminder

		Distribution in survey sample (N= 406[19]) *Column percentage*	Intending to reattend if sent a reminder (N=361[18]) *Row percentage*	Association of testing reminder variable with intention to reattend: P value[20]
TESTING VENUES FOR HIV/STIS				
Preferred venue to HIV/STI test (can pick more than one option)[21]				
GP	Yes	53 (13%)	51 (96%)	0.357
	No	353	310 (93%)	
Home sampling	Yes	143 (35%)	133 (94%)	0.534
	No	263	228 (93%)	
NHS GUM clinic	Yes	335 (83%)	311 (94%)	0.196
	No	71	50 (89%)	
Rapid test centre	Yes	117 (29%)	105 (92%)	0.550
	No	289	256 (94%)	
Private sexual health clinic	Yes	50 (12%)	47 (94%)	0.828
	No	356	314 (93%)	
A+E	Yes	15 (4%)	15 (100%)	0.289
	No	391	346 (93%)	
Other	Yes	9 (2%)	6 (86%)	0.388
	No	397	355 (93%)	
Important factors in deciding where to have regular test for HIV/STI (can pick more than one option)[20]				
Proximity of clinic	Yes	258 (64%)	232 (92%)	0.191
	No	148	129 (96%)	
After hours service	Yes	146 (36%)	136 (94%)	0.756
	No	260	225 (93%)	
Confidentiality of service	Yes	227 (56%)	213 (95%)	0.096
	No	179	148 (91%)	

---

[19] Number (N) is the maximum number of respondents answering a question. The exact number of participants answering the question can be calculated using the column total for each question.
[20] Fisher's exact where cells contain <5 observations. Chi2 test where >=5 observations
[21] Participants were asked to tick all preferred venue. They were able to pick more than one answer. It is assumed that if they did not tick an answer, they did not prefer that option.

Weekend opening	Yes	129 (32%)	118 (92%)	0.546
	No	277	243 (94%)	
Personal recommendation	Yes	75 (19%)	72 (96%)	0.295
	No	331	289 (93%)	
Same day results	Yes	213 (53%)	197 (93%)	0.943
	No	193	164 (93%)	
Option to home sample	Yes	55 (14%)	53 (98%)	0.124
	No	351	308 (92%)	
Previous use of clinic	Yes	179 (44%)	163 (93%)	0.921
	No	227	198 (93%)	
Shorter waiting times	Yes	206 (51%)	188 (93%)	0.580
	No	14 (3%)	173 (94%)	
Other	Yes	14 (3%)	13 (93%)	0.629
	No	391 (97%)	348 (93%)	
Prefer to see clinician or home sample				
Clinician		294 (76%)	266 (92%)	0.130
Home sample		91 (24%)	87 (97%)	
Missing		21	8	

6.4.8 Regression analysis of factors associated with intention to reattend

Explanatory variables were explored for association with intention to reattend using binary regression analysis. Table 14 presents a summary of the regression analysis results for covariates that were significantly associated at the p<0.200 level in univariable analysis with intention to reattend; and covariates included in the final multivariable regression models. Full results are presented in the appendix (table 25).

In the univariable binary logistic regression analyses, the following covariates were associated with increased odds of intention to reattend if sent a reminder at a significance level of p<0.05 (table 14):

- preferring an SMS reminder or email reminder
- liking being reminded to check health status
- wanting a reminder every six months
- a reminder to test in general would increase the likelihood of testing

Not wanting a reminder, concern about confidentiality or stigma were associated with a lower intention to reattend. Of note, numbers in the 'not intending to reattend' group were small reducing the power of he analysis.

In multivariable analysis, covariables included in the final model were:

- reminder preference
- attitudinal questions about liking being reminded to check health status, concern about confidentiality and stigma associated with reminders
- reminder frequency (six months)
- factors that would increase likelihood of testing (reminder in general)

Liking being reminded to check health status, SMS reminders, wanting a reminder every six months, receiving reminders in general and not being concerned about confidentiality of reminders were associated with increased intention to reattend at a significance level p<0.05 in the multivariable model. Concern about stigma associated with reminders was associated with a lower intention of returning for a test.

Table 14: Summary binary regression analysis of factors associated with intention to reattend for a HIV/STI test if sent a reminder

Explanatory variable	BINARY REGRESSION MODEL					
	Univariable odds ratio[22]	95% confidence interval	p value	Multivariable odds ratio[23]	95% confidence interval	p value
SEXUAL HEALTH						
Having a HIV test today						
Yes	REF		**0.132***	n/a	n/a	n/a
No	0.34	0.07, 1.62		n/a	n/a	n/a
Don't know yet	0.79	0.17, 3.59		n/a	n/a	n/a
Ever had an HIV test before						
No	REF		0.253	n/a	n/a	n/a
Yes 1-2 years ago	9.40	0.77, 114.01		n/a	n/a	n/a
Yes, in last 12 months	2.68	0.55, 13.01		n/a	n/a	n/a
Yes >2 years ago	1.6	0.19, 13.24		n/a	n/a	n/a
HIV AND STI TESTING FREQUENCY						
Attitudes to regular HIV testing *Most gay friends test for HIV regularly*						
Agree (strongly/tend to)	2.35	0.98, 5.53	**0.056***	n/a	n/a	n/a
Disagree (strongly/tend	REF			n/a	n/a	n/a

---

[22] Univariable OR are only presented for groups where one covariate has an OR with p<0.2.
* Covariates with p<0.2 in the univariable model were assessed for inclusion in the final multivariable model
# Statistically significant, p<0.05
[23] Multivariable OR are only presented for variables included in the final parsimonious model

to/undecided)						
TESTING REMINDERS FOR HIV & STIs						
Reminder preference (can pick more than one option)						
SMS	14.63	5.66, 37.83	**<0.001*#**	48.73	1.69, 1408.79	**0.024#**
Phone call	0.55	0.12, 2.56	0.452	6.62	0.39, 113,27	0.192
Email	4.41	1.02, 19.01	**0.047*#**	11.45	0.94, 138.79	0.055
Home sampling	0.57	0.16, 2.03	0.386	n/a	n/a	n/a
Don't want a reminder	0.04	0.02, 0.10	**<0.001*#**	n/a	n/a	n/a
Attitudes to testing reminders *Like being reminded to check health status*						
Agree (strongly/tend to)	56.19	12.9, 243.88	**<0.001*#**	59.66	3.92, 908.23	**0.003#**
Disagree (strongly/tend to/undecided)	REF			REF		
Concerned about confidentiality of reminders						
Agree (strongly/tend to)	0.28	0.13, 0.64	**0.002*#**	REF		
Disagree (strongly/tend to/undecided)	REF			29.63	1.41, 619.84	**0.029#**
Concerned about being						

157

stigmatised for receiving a reminder						
Agree (strongly/tend to)	0.20	0.09, 0.47	**<0.001*#**	0.04	0.00, 0.71	**0.028#**
Disagree (strongly/tend to/undecided)	REF			REF		
Preferred reminder frequency (can pick more than one option)						
Every 3 months	REF			n/a		n/a
Every 6 months	11.58	1.50, 89.69.	**0.019*#**	70.96	3.33, 1510.78	**0.006#**
Once a year	3.00	0.49, 18.22	0.233	n/a		n/a
Don't' want a reminder	0.14	0.03, 0.72	0.019	n/a		n/a
Factors that would increase likelihood of testing (can pick more than one option)						
Reminder to test	39.93	5.35, 297.99	**<0.001*#**	24.80	1.56, 392.95	**0.023#**
Recent UAI with CMP	0.34	0.12, 1.02	**0.054***	n/a		n/a
Home sampling kit given at clinic visit for future use	0.59	0.25, 1.41	0.235	n/a		n/a
Home sampling kit sent in post	1.46	0.57, 3.74	0.429	n/a		n/a

Cronbach's alpha for attitudes to regular HIV testing (question D4b,c) was 0.03, suggesting low internal consistency. Cronbach's alpha for perceived behavioural control of reminders (question D6b,c) was 0.72, suggesting high internal consistency between these attitude questions. The other TPB constructs were assessed by one question; therefore Cronbach's alpha was not calculated for these measures.

The multivariable binary logistic regression model had relatively good fit with sensitivity of 96.77%, specificity of 60.00%, positive predictive value of 94.74% and negative predictive value of 71.43% with an overall fit of 95.00%, suggesting that the final model was parsimonious. The probability cut-off was 0.5. Area under the receiver operating curve (ROC) was 0.945 (figure 11), suggesting that the binary regression model had a good fit.

Figure 11: Receiver Operating Curve (ROC) for binary regression model showing the 'goodness of fit' of the binary regression model

Area under ROC curve = 0.9447
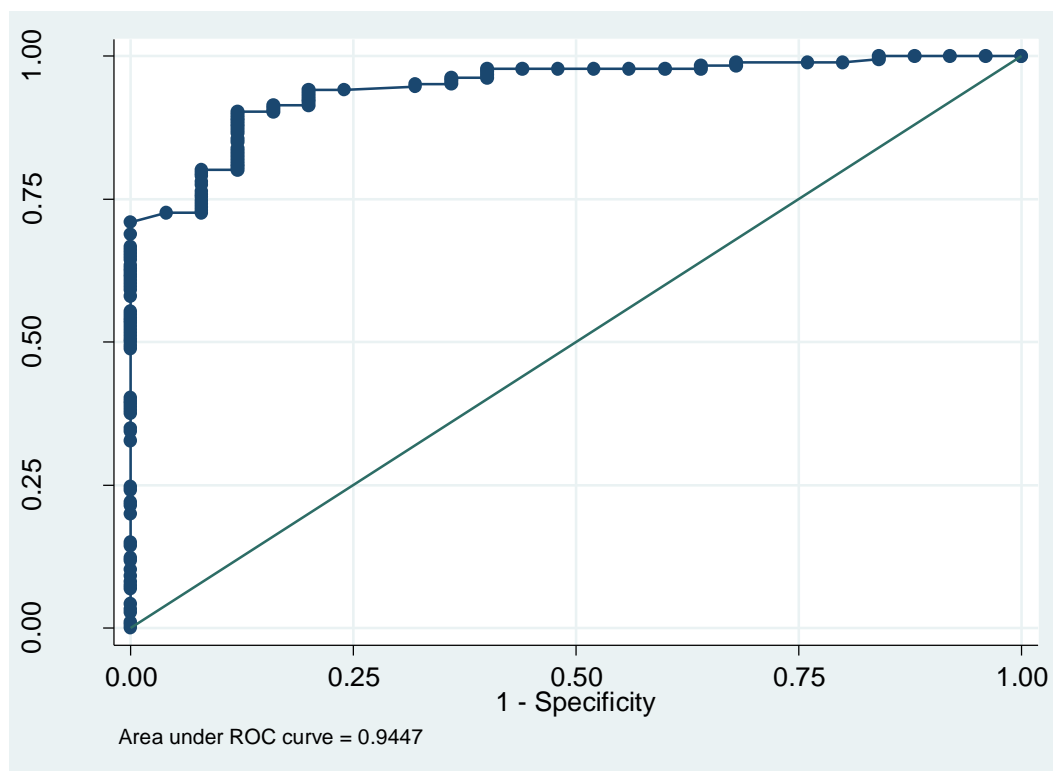
6.4.9 Documented reattendance among SMS active recall recipients

Sixty-seven of the survey respondents received an SMS reminder. One third (23/67:34%) of these SMS recipients returned for a repeat HIV/STI screen three to five months later. All SMS recipients had stated that they intended to return for a HIV/STI screen if recalled

6.4.10 Association between attitudes and documented reattendance

Only having fear of a positive test was associated with reduced odds of reattendance in univariable regression analysis (p=0.019) (appendix table 26). None of the attitudes to testing reminders was associated with documented reattendance in multivariable analysis (appendix table 26). However, the outcome was rare (only 23 survey respondents who received an SMS reminder had a documented reattendance), reducing the power of this analysis.

6.5 Discussion

6.5.1 Summary of results applied to the Theory of Planned Behaviour

The survey highlighted several preferences and attitudes that were associated with intention to reattend. SMS reminders were preferred by the most respondents and preferred testing frequency was every three months.

Constructs associated with intention to reattend included social norms of testing (having gay friends who test regularly for HIV), attitudes to reminders (liking being able to check health status) and perceived behavioural control of reminders (concern about confidentiality and stigma). These constructs were associated with intention to reattend in the descriptive, univariable and multivariable regression analyses, except for social norms of HIV testing which was not associated with intention to reattend in multivariable regression anlaysis.

None of the attitudes to HIV testing was associated with intention to reattend and there was low internal consistency of these measures, suggesting that they were not measuring the same construct.

Other attitudes associated with intention to reattend in multivariable anlaysis included preferring SMS reminders, wanting to test every six months and receiving a reminder to test in multivariable analysis. However, none of these attitudes was associated with documented reattendance. Additionally, preferring an email reminder was associated with increased intention to reattend and not wanting a reminder was associated with decreased intention to reattend in univariable analysis.

However only a very small number stated that they were unlikely to return for a HIV/STI screen if sent a reminder and a small number of survey respondents received a reminder and reattended, reducing the power of these analyses.

6.5.2   Comparison with current literature

In this survey, SMS reminders were preferred by the most respondents, followed by email reminders. The uptake of reminders for sexual health screening has been evaluated in a pilot reminder service for MSM in Australia(177). The 'WhyTest' website gave participants the option to register for a 3, 6 or 12 monthly SMS or email reminder. Approximately half of participants opted for email and half opted for SMS reminders, in contrast to the stated preference in this study. However, a small number of men registered for the 'WhyTest' reminder service and analyses did not explore the reasons for stated reminder preferences.

The theme of responsibility towards ones own health was associated with intention to reattend in univariable descriptive analysis and has been highlighted in several other studies(60, 78, 85, 86). Responsibility is closely linked with other factors related to testing with the participant's life, long-term relationships and community social norms. Participants in some studies have seen testing as a way to remind them to reduce risk(86) or as part of a health routine or maintenance approach(60, 85) as discussed in chapter 2.

Responsibility to others, both new and longer term partners has also been expressed in studies(84), sometimes as a way of proving HIV status(82). The nature of responsibility towards others was not explored in-depth in this survey. Therefore it was difficult to determine whether this was a

responsibility towards casual or regular partners and the reasons for not wanting to put others at risk.

Barriers to active recall associated with decreased intention to reattend included concerns about confidentiality and stigma associated with reminders. The influence of social norms, particularly HIV-related stigma, on HIV testing behaviour has been highlighted by other studies(78, 91). Prost et al found that MSM accessing testing were concerned about being perceived as engaging in higher risk sexual behaviour(290). It is not clear from the survey results reported in this chapter whether the concern about stigma was associated with HIV-related, sexual risk-related or reminder-related (e.g. feeling of being singled out by a reminder) stigma.

Those who did not intend to return for a HIV/STI screen if sent a reminder were also concerned about confidentiality. Text messages have been successfully used in partner notification in sexual health. A survey of partner notification text messages did not report any concerns about confidentiality from recipients(291). However, in a study in which participants were asked specifically about text message content, participants stated that they would prefer the message to ask them to contact the clinic rather than informing them that they have an STI due to concerns about stigma associated with an STI diagnosis(292).

Although the study was underpowered to determine which attitudes predicted documented reattendance, the attitudes associated with intention to reattend may increase our understanding of how and why they might predict documented reattendance. This can be explored further through in-depth qualitative interviews.

6.5.3 Limitations

There were several limitations to this survey. Firstly, only a small proportion of participants did not intend to reattend for a HIV/STI screen if sent a reminder, reducing the power of the analysis to detect factors associated with intention to reattend.

The survey measured intention to reattend, which is not a direct marker of documented reattendance. There may have been selection bias with respondents only completing the survey if they were likely to reattend. There may also have been response bias with respondents answering positively towards reattending as this is encouraged by clinicians. However, the survey was anonymous, and was handed out by reception staff to patients on registration with the aim being that they could complete and hand in the survey before seeing a clinician who may influence their opinions.

All participants who received a SMS reminder stated that they intended to reattend. Therefore, there was inadequate distribution to explore a relationship between intention to reattend and documented reattendance among SMS recipients. Furthermore, only 67 of the survey participants were documented as having received a reminder and of these, only 23 survey participants were documented as reattending at the same clinic within the next three to five months. The small number of survey participants who reattended further limits the power of the analysis to detect an association between intention to reattend and documented reattendance and to detect factors associated with documented reattendance. It is possible that participants did retest for HIV/STIs, but at a different testing venue which could not be captured by clinic records. A small proportion (13%) of the survey sample stated that they had tested at another clinic for their last HIV test, suggesting movement between clinics for STI and HIV testing.

One of the limitations of the Theory of Planned Behaviour is that intention to perform a behaviour does not always predict actual behaviour. This was an exploratory survey. Therefore, each of the constructs (attitude towards testing and reminders, subjective norms of testing and perceived behavioural control of testing and reminders) was explored with a few questions. Social norms of reminders was not explored. Some constructs were only explored with one question; therefore internal consistency of the measure could not be calculated. Furthermore, the internal consistency of the measures of attitudes to testing had low internal consistency, suggesting that they were not measuring the same construct. It is possible that one of the constructs explained greater variance in intention to reattend and documented

reattendance than the others and would need to be explored further. The results of the in-depth interviews in chapter 7 could be used iteratively to inform a further, more focused survey that explores each of the constructs of the TPB in more detail.

The survey was not able to explore association of the TPB constructs with documented reattendance due to the small number of survey participants who reattended. A further longitudinal study with longer follow up would be required to understand the contribution of the TPB constructs to explaining reattendance.

A body of literature also suggests that moral norms can influence intention as well as social norms(293); moral norms were not explored in this survey. Moral norms are the rules of morality that people are expected to follow. They can be positive (e.g. protect the health of others as you would wish them to protect you) or negative (e.g. do not harm others).

The survey used validated questions as far as possible. However, the survey tool was not validated. Before the survey or questions from the survey can be used as a screening tool to identify those at risk of not reattending for a HIV/STI screen, questions that predict actual/documented reattendance (as opposed to intention to reattend) would need to identified and validated. However, this would require a longer prospective study.

The Theory of Planned Behaviour is a static model with intention predicting immediate behaviour(294). However, in this survey, there was a three-month time gap between stating intention to reattend and documented reattendance. In that time period, the constructs being measured (attitude to testing, subjective norm and perceived behavioural control) may have altered somewhat.

Question C9, which asked about the numbers of CMP with whom the respondent had receptive UAI, was poorly answered. Participants appeared to misunderstand the question, often just ticking an answer rather than providing a number. This was not identified in cognitive interview, possibly because cognitive interview participants spent longer reading the question carefully

than survey respondents. Therefore, the results for this question are taken only from those participants who were able to correctly complete all fields, limiting the representativeness of the question.

Finally, not all eligible MSM attending clinic answered the survey. The survey was distributed by clinic reception staff; it is possible that the survey was not offered to all clinic attendees, particularly on busy clinic days. Although survey respondents were encouraged to place blank uncompleted surveys in the survey collection box in clinic, or tick that they did not consent to completing the survey if they did not wish to complete it, some clinic attendees may have thrown a blank survey away. No surveys were completed outside clinic and posted back to the researcher.

It would be useful to compare the participant characteristics of the survey population to non-consenting and non-participating clinic attendees, to understand whether the survey participants were representative of the clinic population or if there were systematic differences between the groups. Only six men who returned a survey, and were eligible to take part in the survey (i.e. had not previously completed it, were male, reported sex with men and were HIV negative) either did not consent to completing the survey or did not record their consent. However, ethics approval was not obtained to extract data on clinic attendees who did not participate in the survey or who ticked that they did not consent to completing the survey. Nevertheless, the median age of survey participants (median age 34) was similar to the median age of clinic attendees in the service evaluation in chapter 5 (median age 33). In making this comparison, it should be recognised that the time period in which patients attended clinic is different for the service evaluation and survey groups.

The population answering the survey was highly educated, 70% had a university degree or higher. This may be reflective of the clinic demographic; the clinic is based in central London surrounded by several universities and professional workplaces. However, there may have also been response bias with more educated patients choosing to complete a written survey. Therefore, answers may not be generalisable to the target clinic-attending

MSM population in England. The survey explored the drivers and barriers to active recall for HIV-negative MSM who were already engaged with sexual health clinics. A key exclusion criterion was MSM diagnosed with HIV, who may also benefit from active recall for STI screening. However, findings from this survey may not be generalisable to this population. Furthermore, the findings from this survey may not be generalisable to MSM who do not attend sexual health clinics since the intervention of active recall requires the recipient to have attended a sexual health clinic.

Finally, only 108 (26%) of survey participants could be linked to their clinical records. Therefore, it was not possible to obtain information on acceptance of an SMS reminder and reattendance rate for almost three quarters of survey respondents. The analysis of attitudes associated with documented reattendance may therefore not be representative of all survey participants. It would also be useful to link survey data to the sexual risk of survey participants recorded in the clinical risk assessment to determine which survey participants report were eligible for an SMS reminder and the SMS reminder uptake rate.

6.6 Conclusion

The survey highlights several attitudes associated with increased intention to reattend if sent a reminder. These include preferring SMS reminders, liking being reminded to check health status, not being concerned about the confidentiality of reminders and preferring to have a reminder to test. However, concern about stigma was a barrier to reattending if sent a reminder. SMS reminders were preferred by the most respondents and preferred testing frequency was every three months. The survey was not able to explore the reasons why these attitudes were drivers or barriers to testing if sent a reminder and the reasons for why an SMS reminder was preferred. These are explored in the next chapter through in-depth interviews.

The attitudes associated with intention to reattend were not associated with documented reattendance. This may be due to the low power of the analysis due to small numbers of survey participants who stated that they did not

intend to reattend and the small numbers who received a SMS reminder and reattended. However the reasons can be explored effectively through in-depth interviews.

The in-depth interviews in the next chapter explore some of the attitudes to HIV testing and reminders that were found to be associated with intention to reattend in the survey, and to understand the nuanced reasoning behind the findings of the survey.

Chapter 7   Study 3: In-depth interviews

7.1 Introduction

The results of the questionnaire survey described in chapter 6 outlined some of the drivers and barriers to returning for a HIV/STI screen when sent a reminder. Preferring SMS reminders, liking being reminded to check health status, not being concerned about the confidentiality of reminders and preferring to have a reminder to test were drivers associated with intention to test if sent a reminder. Concern about stigma was highlighted as a barrier to reattending if sent a reminder. However, the attitudes associated with intention to reattend were not associated with documented reattendance, albeit that the statistical power was low due to the small numbers included. The survey was unable to explore a relationship between intention to reattend and documented reattendance, as all participants who received a SMS reminder had stated that they intended to reattend.

The in-depth interviews explored the nuanced reasoning behind why the drivers and barriers might influence reattendance. The interviews also explored the reasons for preferring one type of reminder over another. The themes highlighted through the interviews were used to understand whether the Theory of Planned Behaviour, as proposed in chapter 2, might go some way to explaining reattendance behaviour for HIV/STIs when sent a reminder.

7.2 Aim

The main aim of the in-depth interviews was to explore the drivers and barriers to testing and active recall reminders. Specific objectives were:

1. To explore what are the drivers and barriers to testing, testing frequency and active recall reminders and how and why they influence intention to reattend

2. To explore the contextual factors that influence the drivers and barriers to testing, testing frequency and intention to reattend if sent an active recall reminder

7.3 **Methods**

7.3.1 **Sample selection**

A total of 16 interviews were planned using purposive sampling to ensure diversity of key socio-demographic and behavioural variables thought to influence re-attendance. A selection matrix was used to inform the sampling strategy. The selection matrix is outlined in table 15. The sample population was sourced from those who consented to taking part in in-depth interviews in the questionnaire survey. Contact details of individuals who consented in the questionnaire survey were obtained from the NHS database. It was planned to select participants for interview using the primary and secondary selection criteria outlined below.

Primary selection criteria included sexual risk behaviour (unprotected anal intercourse (UAI) with a man in the past three months), and behavioural intention (intention to return for a HIV/STI screen on recall) as outlined in the selection matrix in table 15.

Secondary selection criteria included key demographic variables, such as age and ethnicity. However, the sampling frame was driven by the primary sampling criteria.

Four interviews were planned in each cell of the selection matrix (table 15).

Table 15: Selection matrix for in-depth interviews

		Sexual risk behaviour	
		Unprotected anal sex in past 3 months	No unprotected anal sex in past 3 months
Intention to return for a test after recall	Yes	4	4
	No	4	4

7.3.2 Development of topic guide

A topic guide was developed based on the conceptual model outlined in the introduction chapter, which was based on the Theory of Planned Behaviour(10). This included the domains of attitude to the behaviour (retesting/re-attendance), social norms and perceived behavioural control.

These domains were explored within three main sections of the interview: exploration of sexual risk and lifestyle, HIV testing patterns and experience with and attitudes to healthcare reminders. Since HIV/STI testing is a topic that most sexual health attendees are familiar with, enabling techniques were not used. Examples of enabling techniques might include asking the respondent to project their beliefs onto an imaginary person or situation. The topic guide can be viewed in the appendix (appendix 5.2).

7.3.3 In-depth interviews

The in-depth interviews were conducted over a two-month period by the researcher, MD who was trained in the technique. The interviews were audio-recorded and limited field notes were taken during the interview. Interviews aimed to gain breadth and depth, and used both pre-defined and ad hoc probing questions where necessary to support the interview process. All interviews were anonymised and transcribed verbatim externally and reviewed by the researcher for accuracy. One interview (IDI_009) only partly recorded and field notes were recorded immediately after the interview.

7.3.4 Data management

Data were indexed and coded into themes using an iterative process to develop the final coding tree. One person (MD) performed the interviews and

data coding. Coding matrix queries were performed to facilitate cross-case data analysis. Data management was facilitated by a computer-assisted qualitative data analysis software package (CAQDAS), Nvivo.

7.3.5   Data analysis

Data were analysed using a form of thematic analysis outlined by Ritchie et al(207). Descriptive and typological analyses were conducted to allow explanations for the association between attitudes to reminders and testing for HIV/STIs to be explored.

7.3.6   Consent and confidentiality

The study was reviewed favourably by the Leeds West Ethics Committee (REC reference13/YH/0347, appendix 4.1). All participants received a patient information sheet (appendix 5.1) in advance of the interviews and signed a written consent form prior to taking part in the interviews (appendix 5.3).

7.4 Results

7.4.1   Participant characteristics

Sixteen participants were interviewed in total. However, as participant selection was limited by patient consent to interview, the final numbers in each cell in the selection matrix changed from planned as reflected in the participant characteristics. All age groups were represented. A third reported UAI with a casual male partner (CMP) in the past three months, a quarter had received a reminder for testing from the clinic and the majority (87%) stated that they intended to return if sent a reminder in the questionnaire survey (table 16).

Table 16: Key demographics of in-depth interview participants

	Number	Percentage (%)
Age		
18-25	2	13%
25-30	3	19%
30-35	2	13%
35-40	3	19%
40-45	2	13%
45-50	1	6%
>50	3	19%
UAI with CMP		
Yes	6	37.5%
No	10	62.5%
Reminder experience		
Yes	4	25%
No	12	75%
Likely to reattend if sent reminder on questionnaire survey		
Extremely likely	11	69%
Quite likely	3	19%
Not very likely	2	13%
Extremely unlikely	0	0%

Respondents included those who had become sexually active both early and late in life, three participants were bisexual and one transsexual (male-female) undergoing gender reassignment.

7.4.2 Themes from in-depth interviews

7.4.2.1 Attitudes to testing and testing frequency

Identifying the source and early diagnosis

A positive attitude to testing and deciding on testing frequency was being able to identify the source of a presumed or actual infection. In some cases wanting to know who the source of an infection was enabled the respondent to think about partner notification. Being able to blame a possible source of infection was implied, but not explicitly mentioned even when probed.

> 'If I come in after twelve months and it's positive, I don't know where I got it, you know it could have been ten, twelve, thirteen people.' (IDI_013)

Respondents wanted to test to find out their diagnosis early so that they could access care and medication early. This was linked to medical advice and knowledge about early care and association with better outcomes, especially for HIV.

> 'I understood that you need to basically have an early diagnosis in order to treat, to be treated and as I was having casual sexual encounters I just thought it made sense, given particularly things like not only HIV but Hep C and stuff like that, just to get tested' (IDI_007)

The concept of early diagnosis was also linked with staying healthy. Some saw testing as part of their personal care or routine.

> 'Just to sort of be safe and I find it a little bit of a sort of cleansing experience. I like going and I like coming out the other side and knowing I still don't' have anything' (IDI_001)

Respondents wanted to be treated for an infection early to maintain their quality of life.

> 'Nobody really wants to be ill…I can't function in my life unless I am healthy, so keep yourself healthy, and I would rather know if I have got something. I would rather know about it so I can deal with it' (IDI_016)

<u>Conflict with trust</u>

Many respondents tested for HIV and STIs when starting in a new relationship or at the point that they wanted to stop using condoms, but often felt that this conflicted with the sense of trust in the relationship. The majority of respondents felt that testing for HIV/STIs breached the trusting bond in a monogamous relationship. For some, this conflict between wanting to stay healthy and trusting their partner made them weigh up the relative risk of getting an infection and not knowing about it with the benefit of being in a trusting relationship. It was rare for respondents to see the two concepts- trust and staying healthy- as complementary to each other.

> 'If you're going to have a trusting relationship you need to trust the other guy and of course it means that you get it…well, get HIV but at least you've been trusting him and that's worth it because that what life is about' (IDI_009)

The concept of trust with a regular male partner (RMP) was a strong theme for men reporting no UAI. Respondents frequently mentioned the concept of being in a monogamous relationship and wanting to trust their partner acting as a barrier to testing; testing brought up questions of fidelity.

> "I was with a steady relationship, there's probably much less need to actually go back as regular, it's more your own piece of mind, it's obviously not, you're not, if you were in a complete monogamous relationship, I suppose you could trust them pretty much completely" (IDI_006; reported no UAI)

<u>Fear/embarrassment</u>

Fear about a positive diagnosis and uncertainty about what to expect from the consultation, tests and medical staff tended to be barriers to testing for the first time. Respondents expressed denial, not wanting to know their status or being so consumed by fear of a positive result that this acted as a barrier.

This was overcome by attending a clinic, often with support from friends or peers. However, for some people taking this step took time, and was

triggered by personal events such as being contacted by a sexual partner with an STI or feeling low.

> 'it was absolute nightmare of three weeks, I been through until I get the courage of one of one of my friends they said come on, do it, what is worse, if you are believing that it is already, you are infected' (IDI_003)

Embarrassment about discussing sexual history and risk was expressed as a barrier to testing early on in a respondent's testing history. For some, the embarrassment was present at most sexual health consultations, but was overcome by approachable medical personnel. Respondents also realised the importance of accurately reporting their sexual history to medical staff to allow them to be assessed appropriately. Avoiding the embarrassment of disclosing sexual history was noted as an advantage of self-sampling.

> "He was so embarrassed to come to, to take the first step, I remember myself, years ago, it was difficult for person never had to be tested before, to come the first time to do the test, but as soon as it happens, it see how quick it is, and how piece of mind it give you, you just say I need to do it" (IDI_003)
> "I was like 'But I ... I don't want to', because like in the last month I don't know how many people I've seen, and then you start to feel an embarrassment about it" (IDI_012)

7.4.2.2   Social norms of testing

Responsibility to others

Responsibility to other, both individual partners and to the gay community in general was a common theme that reflected social norms. The concept of responsibility to others was closely linked to staying healthy. Respondents felt that by staying healthy, they could prevent spreading the infection to others and felt a sense of responsibility about this.

> 'I want to be healthy and I don't want to be the reason to destroy other peoples lives' (IDI_003)

Responsibility to the gay community was expressed as a communal sense of responsibility.

> "I want to do as much as possible to make sure that I don't have anything so I don't pass it on to other people either. I think its like a, how can I put it, its something that we should all do and keep the thing cleaner and keep the gay scene cleaner." (IDI_010, reported UAI)

When trying to protect others, respondents were aware that they could transmit infection to others during the period between tests and wanted to minimise this risk.

> 'People don't know if they catch things like HIV, you know if you catch it you wont even know that you are carrying it. So the sooner you get it treated the better it is for you and other people' (IDI_014)

<u>Medical advice</u>

Respondents expressed trust in medical advice. They often quoted what they had been told about recommended testing intervals, window periods and high-risk sexual behaviours by clinicians and in the gay press. This was also reflected in concerns about using other testing modalities such as self-sampling; participants who were concerned about using self-sampling did not want to lose contact with medical professionals.

Medical advice was received through clinic visits, in the press or from friends with a medical background. Respondents were often aware of the reason for this medical advice and able to reference the HIV testing window period.

> 'Now I tend to test every 6 months that is what I used to be recommended here in this clinic years ago so then I kept it like that. Now this time when I came back they told me to test every three months and because I trust them I am going to have to do it every three months' (IDI_010)

Men reporting UAI with a CMP were highly influenced by medical advice. This may be associated with increased contact with medical teams due to symptomatic infections or increased health promotion and testing advice

offered to men who report UAI with a CMP by healthcare professionals. National guidance on behavioural interventions recommends the use of brief interventions for MSM who report UAI with a CMP; evidence for motivational interviewing for this group is conflicting(36, 295).

> "Reason for testing is as I say you know the NHS says it's a good thing, you know it is better a) to get yourself treated and b) to know if you've got something that can't be treated, and c) to not pass things onto other people that's kind've a good thing. I did have an episode of Hepatitis C that wasn't caught by check-up it was caught by the fact I was symptomatic, but that of course emphasised the importance of doctors. " (IDI_011, reported UAI)

Concerns about wasting resources

A common theme to emerge was concern about wasting NHS resources and taking services for granted, especially if test results were negative. This was partly linked to risk perception as participants with lower risk behaviours expressed this as more of a concern. However, there was some acknowledgement that prevention through routine screening may be cost-saving. Another theme, though less common, was a concern that by testing respondents were passing responsibility for their health onto the healthcare profession and negating their own responsibility.

> 'I feel that if I came here every three months, or every two months, that…it's like I'm wasting the NHS's time…because…in the majority of instances it's okay.' (IDI_005)

> 'a little bit of me is saying well this is me having recreational sex, this is a pleasure, I don't have to have recreational sex and the NHS doesn't have to underwrite me for it' (IDI_011)

Perceived behavioural control of testingAccess

Access was a major barrier to testing, and took the form of long distances to a clinic, inconvenient clinic opening times and long clinic waiting times.

Difficulty making or accessing an appointment or having to wait several weeks for an appointment was a further barrier.

> 'Life is hard enough for most people in London. They don't have much free time. If you have to take an hour out of your time, particularly during the working day when most clinics are open, you know very few clinics have late in the evening or weekend services and you know, when you go late in the evening or the weekend, you have to queue for two hours because the service is so popular.' (IDI_007)

Not only was access a barrier to testing overall, but also a barrier to frequent testing. Many respondents felt that they tested less often than they intended to because of the time taken to have a regular test. As a result, many respondents tested infrequently or only when they had symptoms.

> 'Well I'm very busy. The clinic is an hour away. When I get there I'll probably have to wait for two hours, you know, this is a 4,5 hour round trip effort. "Oh I'll go next week" becomes next month and next quarter or next year, for example, and, even though somebody like myself, who's cognizant of the importance of having regular tests, is likely to find it hard to stick to that' (IDI_007)

Examples of access facilitating testing included weekend or late opening and rapid testing. This allowed respondents to fit testing into their lifestyle with minimal disruption. Short waiting times at times convenient to the tester were particularly important. Some respondents were opportunistic in their testing behaviour if they lived close to or were passing by a clinic and were able to have a test rapidly.

> 'to come at lunch time, come in, immediately be seen, quickly go through it all, whiz through and out the door as fast as possible…for me work time is usually of the essence, so it's sort of speed and also the control of it.' (IDI_001)

> 'I went to the one in Southwark that's open on a Sunday and that was lovely. I remember thinking God this is a really nice GUM clinic. Saw

me straight away, Sunday morning and I was in and out the door and I thought at the time, oh, this is lovely.' (IDI_001)

Men who reported no UAI particularly commented on wanting to be seen quickly, wanting out of hours access to clinics such as evenings, weekends and lunchtime and proximity of the clinic to work or home as being important factors in deciding to test. Some respondents described being tested as a routine thing to do if it was made into a simple task.

In contrast, men who reported UAI commented on the importance of access when they did not have symptoms, but were less concerned about access when they needed to seek medical help.

Self-sampling and home testing were associated with easier access, as the barriers associated with being seen in clinic (e.g. waiting times, clinic opening times) could be avoided. However, respondents were clear that they would only use self-sampling if they were asymptomatic, wanted to exclude infection if they had symptoms (as opposed to detect an infection) or did not require medical advice. Men who did not want to use self-sampling were concerned about losing medical input, and expressed concerns about accuracy of the test or their own ability to conduct the test properly.

> 'If I don't have any symptoms and I have a home testing thing, I'm probably much more likely to do it than, you know, have to take two hours of the day to come in' (IDI_004)

Men reporting no UAI commented on the benefit of being able to ask medical professionals questions about their sexual health when they tested for HIV/STIs and were concerned about the loss of health promotion through self-sampling.

> 'I think home testing personally is bad because it isolates people from doctors … I just think that home testing is just not good because there are doctors out there to make sure that regardless of you knowing what is in your own interest, they can tell you.' (IDI_012, reported no UAI)

In contrast, men reporting UAI were interested in using self-sampling as a quick means of testing when they had symptoms that they were concerned about to exclude infection.

> 'I do like the idea of having a kit on standby, I think, if, you know, you did get symptoms and you know, you didn't have time to come in immediately or something, so my, if they were doing that, if they said look, take your kit away and if you get symptoms, do this, and I might go for that' (IDI_013, reports UAI)

One respondent who stated that he was unlikely to reattend if sent a reminder highlighted that on several occasions that access to the clinic was a barrier to him attending. He felt that it was only necessary to test for HIV/STIs if he had symptoms as he was unlikely to have an infection if he was asymptomatic. As a result, he felt that any benefit of testing when asymptomatic was outweighed by the inconvenience of accessing testing in a clinic.

> "Why would I take time off if I have got nothing wrong" (IDI_014)

He had tried home sampling and found it a positive experience due to the convenience of testing at home and the time saved by not going to clinic. However, the option of home sampling did not change how frequently he would test as he was happy with his current testing frequency.

7.4.2.3 Perceived behavioural control of reminders

Participants were asked about their attitudes to reminders by asking them to talk about what they understood by reminders. They were asked to recall their experience with reminders, how they remind themselves about appointments currently and their views on different types of reminders such as email, SMS, postal, phone reminders and self-sampling.

Examples of reminders respondents had received were SMS from the clinic or from a dentist. Some had received a postcard from dentists. Often the reminder acted as a prompt, but the respondent had already intended to retest. The reminder may have expedited retesting, but did not initiate it.

'the last time I came for an HIV test here is when I had had unprotected sex with someone, and they said…if you want us to send you a reminder in three months, which they did, then I came in for a finger prick test on that occasion….but maybe if they'd said come back in three months, maybe, I don't know, I think I would have come eventually, but maybe not in exactly three months' (IDI_013)

There were several themes that emerged as important to all respondents about reminders in general and were relevant to all types of reminders- SMS, postal, email, phone and being sent a self-sampling kit/receiving a self-sampling kit in clinic for later use. These were convenience, confidentiality, control and reminder persistence.

Convenience

A common theme was the need for reminders to be convenient and minimal work for the recipient. Participants preferred reminders that could be received and accessed at any time of day with minimal interruption to their daily life.

Respondents who preferred SMS reminders liked that they could be received at any time of day on a mobile phone and that the recipient could store the message as 'unread' to action at a convenient time later in the day. SMS reminders were considered easy to use, as participants could click on a phone number link or hyperlink in order to call the clinic to make an appointment. This was in contrast to emails where the volume of emails deterred some participants from trying to find an important email later in the day or the message could get lost in the volume of incoming emails.

'I think that the joy of it coming through by text or on a mobile phone is its so simple and you sort of, it removes that element of thought, so even … a text message…(has) a link in the phone with a phone number on… most phones you can highlight a number and call it' (IDI_001)

In general respondents preferred not to receive a phone call as it either interrupted their working day or they had to return a call at a later time. This required effort and may encounter barriers such as engaged phone lines. All

reminders required a phone call to clinic to book an appointment unless an automated system could be developed with a text or email link to a booking service. An on-line booking system was seen as convenient as it could be accessed at a time of the day most convenient to the user. Needing to make a phone call to clinic to book an appointment was perceived as a barrier.

> 'If it had been a link I probably would have done it there and then and I could have very quickly just quickly done it on my phone, done, in for next week, but it was the extra effort of having to call up, find somewhere private to do all of that that kind of added an element of, delay on the process. The other thing I quite like about being able to book on-line is you could, I could then say right Thursday at 12. If Thursday at 12, say in two weeks time and then realise its not okay, I can just move it myself whereas having to call up and kind of go through that faff makes it a lot more sort of, I might just say just leave it for now, I'll call up again when I know whether I'm going to be a bit quieter.' (IDI_001)

Self-sampling was seen as a convenient way of testing. It avoided the barriers highlighted earlier with coming into clinic, such as long waiting times and access. Some compared it to an administration task that they would do as part of their regular day-to-day activities, requiring little additional effort. However, respondents were clear that the convenience of self-sampling would not outweigh coming to clinic if they had symptoms that they were concerned about.

> 'If I don't have any symptoms and I have a home testing thing, I'm probably much more likely to do it than, you know, have to take two hours out of the day to come in and, you know, do something that I think may not achieve anything' (IDI_004)

> 'Because of the lack of bother…a home test the way I picture it is very simple, I can't think of any reason why I would delay it, it would for me in my head you know we all have these domestic admin jobs the paperwork of life that in my case every few evenings having to sit down and spend half an hour doing them and it would do into the cagegory of

that, it would go into the category as I say going online and paying a bill it takes a few minutes to do' (IDI_011)

<u>Confidentiality</u>

Confidentiality was extremely important to respondents, especially when receiving reminders during the working day. SMS reminders were seen as confidential as they were received on a personal phone. Some respondents noted that often only the first line of the text or the text heading appeared on their screen. Furthermore, they could set their text message preferences to only show the respondent's name or number meaning that the message would not show up on their phone, increasing confidentiality.

Emails were seen as less confidential, especially if they were sent to work emails. This was either because work colleagues could access work emails or because emails 'popped up' on screens which could be read by others.

There were concerns about the confidentiality of letter reminders, especially about other people opening mail if there is communal post delivery. Some respondents were concerned about friends or relatives seeing the letter and incorrectly assuming that the recipient is HIV positive. There were concerns that partners could become suspicious if they saw the letter or could persuade the recipient of the letter that they did not need to have a test.

> 'No I wouldn't like that because... in my case letters go into the floor of the entrance and anyone can take them and anyone could read them. A bit like the email it's more exposed but this is even more because anyone could steal it from you' (IDI_010)

> 'If my family saw a letter addressed to me about HIV…I think they would think I was HIV positive' (IDI_013)

> 'A letter's probably going to be post-marked with, you know, the NHS Trust's, you know, franking machine or whatever it is, so again that might create problems in suspicious partners' (IDI_004)

Similarly, some expressed a concern about the confidentiality of self-sampling kits if they were left out or received in the home environment. This was

particularly a concern for people sharing accommodation with others, if family were visiting or if they had not disclosed their sexuality.

> 'The paraphernalia of testing (in the) home environment might lead to questions from people they share an apartment with…you may be uncomfortable discussing these type of things with other people or even perhaps, in this day and age, some people are still in the closet and therefore, don't wish to have those kids of discussions or those type of indicators around in their home environment' (IDI_007)

Men who reported no UAI expressed a positive attitude about the confidential nature of email. In contrast, men who reported UAI expressed some concern about people wrongly assuming that they had an infection and expressed more concerns about being embarrassed if a reminder email was seen by others.

> "I think it's very personal. Your sexual health is very very personal. Like your dental health really but with the sexual there is a bit more embarrassment about sharing that." (IDI_010, reported UAI)

Concern about privacy and stigma was voiced among respondents who did not intend to return if sent a reminder. They were concerned about people seeing the reminder, and this was equally true for letters, SMS and emails. There was a concern about how people, including friends, would judge them. One respondent was bisexual and felt that he should marry a female. He was concerned that a reminder encouraging him to test may disclose his sexuality to friends and family.

> "There is a bit of worry... what if people see this kind of thing, what would they think of me and how would they judge me and all that and I don't want them to see my personal life, you know private life." (IDI_014)

Control

Control was a key theme that respondents valued about a reminder. They wanted control over how and when they received a reminder and how they

could respond to it. Most respondents preferred to have an automated system that would allow them to book a reminder appointment through an electronic link, and some likened this to making a restaurant reservation.

> 'If it's just a regular check-up or for something sort of non-urgent, I love being able to book on-line and it's so straightforward. You usually get an email confirmation which is something you don't get on the phone and then with the email confirmation there's usually an add to your calendar button and it goes into my iPhone and I get a reminder and then I'm here, so it just sort of modernises the whole process' (IDI_001)

Respondents wanted control over the type and frequency of reminder they received, either setting this preference at each clinic visit or having an on-line personal web page that they could update. In general this was so that the frequency of reminders could match their perceived sexual risk. For some this was also so that they could create a complimentary system to their current reminder system.

> 'I would love a profile on-line. I would love to be able to see kind of some of my records or anything like that, just have my information available to me and then I could go on-line, log in, adjust my contact details, e-mail address, phone number, whatever I wanted, see when I last came, if I wanted to kind of see my book or my next appointment and then adjust kind of methods of communication based on anything, just a profile like you have in every other area' (IDI_001)

One respondent who stated that he did not intend return if he was sent a reminder by the clinic felt that he already had a suitable reminder process in place. He had set up a calendar reminder system for a six-monthly reminder for a sexual health screen, which gave him control over his testing behaviour. He felt that a reminder from the clinic would not have added value and could be perceived as an 'annoyance'.

> "it's almost spamming, yeah that's how I would see it. The other one on the contrary is education" (IDI_014)

He preferred a health promotion reminder, as he felt that it had added value. A health promotion message was perceived as educational and empowered the recipient. Examples of health promotion messages included those that educated the recipient about the risks associated with unprotected sex. This view was expressed by other respondents too.

> "What would be beneficial maybe is to have reminders of being careful with sex...just the education part, use protection, if you don't use protection what can happen, these are the consequences, remind me of that" (IDI_014)

Reminder persistence

Reminders that had visual persistence were seen as important to facilitating retest or reattendance. Items that had visual persistence were those that were visible after the reminder had been received.

For example, SMS reminders were described as having visual persistence as they remained in participants' inboxes until they had been viewed. Participants could also programme their inbox to keep the SMS active until it had been actioned. SMS reminders were also seen as requiring a more immediate response or action. For some people this was because they receive less text messages than emails and are less likely to get spam SMS messages. Therefore they feel more obliged to respond to or act upon an SMS message compared to an email. For others it was because SMS messages are received and read on a phone at any time of day, whereas emails are checked at set points in the day. As a result, an email could be one of many and easily discarded, whereas all SMS messages are read in full.

> '(SMS) are more immediate wherever you are for me the way I do things wherever I am a text message comes in and you're sitting on the tube and read it. Emails I do at a particular time of the evening I'll sit down and go through the emails and it's more of a chore for me,' (IDI_011)

Self-sampling kits were described as having visual persistence as they acted as a reminder each time the respondent saw them in their house. Some respondents commented that they would be more likely to perform self-sampling on time than come to clinic because of the visual persistence of the kit, combined with convenience and control.

> 'Every time I open the kitchen cabinet to get the-, the bathroom cabinet to get the kit-, to get-, or brush my teeth or get some ointment or something, I'd see the kit in the cabinet, I'd have a quite look at the date and say, "Okay, well about now, or round about this time, I need to perform this test. Go ahead and do it."' (IDI_007)

7.5 Discussion

7.5.1 Summary

In this chapter, the in-depth interviews explored attitudes to testing for HIV/STIs when sent a reminder and the attitudes to reminders and their influence on testing behaviour within the context of attitudes to testing.

Reasons for testing frequency broadly fell into three themes: identifying the source of potential or actual infections, medical advice and responsibility to others. Reasons for testing were closely linked to reasons for testing frequency e.g. early diagnosis and staying healthy/responsibility to others. Drivers for testing included access, the influence of peers or a regular male partner. Conversely barriers included conflict with trust, access, fear/embarrassment and concerns about wasting resources. Key themes in responding to reminders included convenience and confidentiality of reminders, control over the reminder and reminder persistence.

7.5.2 Conceptual model

The themes identified in the in-depth interviews allow development of the conceptual model outlined in chapter 2 (figure 12).

The attitudes to testing, social norms around testing behaviour and frequency and perceived behavioural control of testing, combined with perceived

behavioural control over a reminder determines whether a recipient consents to receiving a reminder.

For example, a person needs to have a positive attitude to testing (e.g. wants to identify the source of their infection, wants to be diagnosed early with an infection). This is counterbalanced by the negative attitudes of fear/embarrassment. A positive social norm to testing (e.g. medical advice, a sense of responsibility to others, influence of others and not wanting to waste resources) will positively influence testing behaviour. Furthermore, the person needs to have positive behavioural control of testing by feeling that they will be able to access testing (for example through confidentiality and ease of accessing testing). If they also feel that they will have control over a reminder, they are more likely to consent to receiving a reminder and have intention to reattend. Therefore, the reminder needs to be delivered in such a way that the participant is confident that it is confidential, convenient and provides the participant with control over how to respond to the reminder (e.g. through an interactive on-line booking system).

However, once a patient who intends to reattend receives a reminder, their actual reattendance is determined by their perceived behavioural control over the reminder and accessing testing. Therefore, the reminder needs to be confidential, convenient, persistent and provide the recipient with control to access an appointment. This last theme (control to access an appointment) overlaps with perceived behavioural control of testing; access was an important driver and barrier to testing in the interviews.

Figure 12: Modified conceptual framework of the influence of attitudes, social norms and perceived behavioural control on testing behaviours/frequency and its influence on reminders and intention to retest
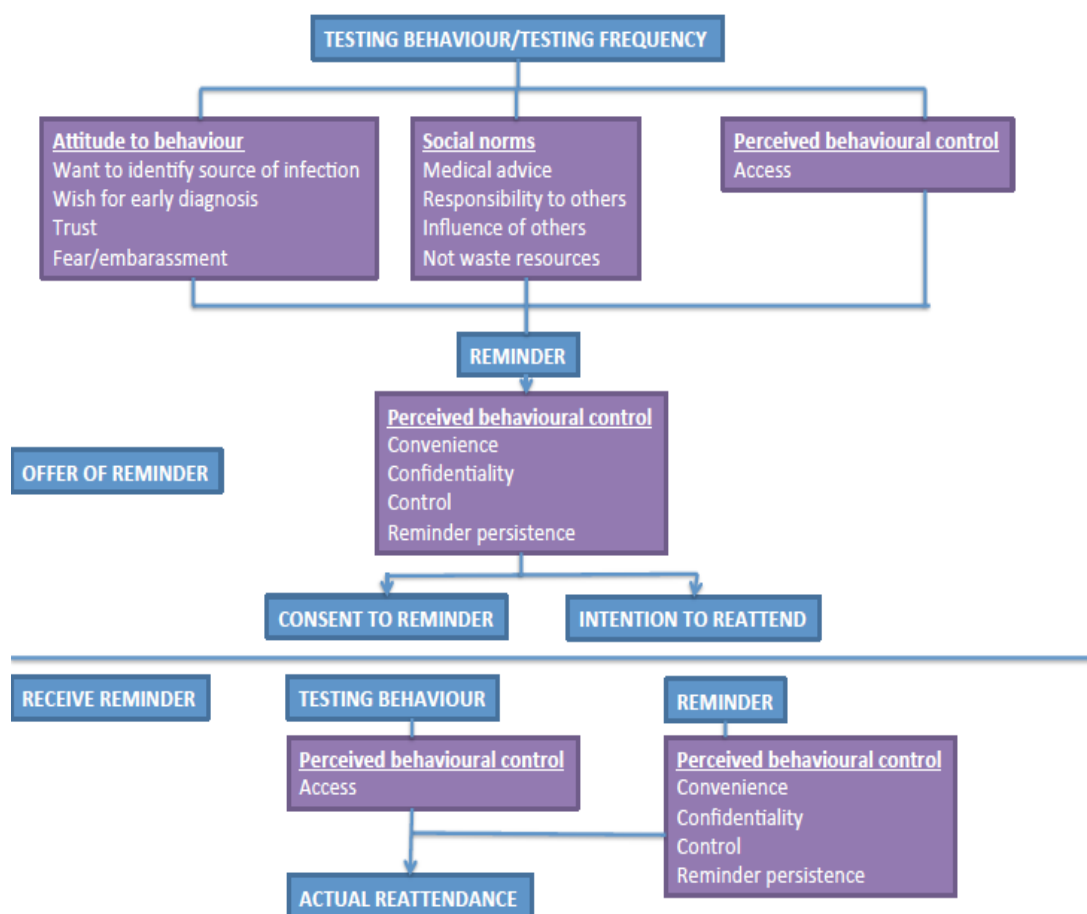
7.5.3   Comparison with current literature

Reasons for testing and testing frequency

Several studies have explored the drivers and barriers to HIV testing and HIV testing frequency and have highlighted similar themes to those seen in this study.

A major reason for testing in this study was a sense of responsibility to others to limit spread of infection to partners, and also to the gay scene in general. However, this conflicted with a sense of trust within a monogamous relationship. Participants felt that testing for HIV/STIs would question the strength of their relationship. This is reflected in a body of literature that demonstrates that MSM in partnerships are less likely to have regular HIV tests than MSM who are single(102), despite data demonstrating that most HIV transmissions among MSM in the United States are from main sex

189

partners(104). Similar barriers to testing have been highlighted in a systematic review of qualitative evidence that looked at drivers and barriers for HIV testing(60, 78). In a study by Lee et al, participants who perceived each other as 'responsible' in a relationship did not test as regularly and sometimes took increased sexual risk justifying it as a consensual decision based on trust(60). A sense of responsibility to oneself through a desire for early diagnosis and access to care or making testing part of routine care regardless of whether they had a risk exposure or symptoms has also been a theme in other studies(60, 78, 85, 86). Lee et al's 'health maintenance' approach(60) suggests that MSM who report UAI with CMP would not utilise a 'health maintenance' approach as readily as MSM who take less sexual risk since men who take a 'health maintenance' approach will engage in less risky sexual behaviour. A cross-sectional study by McDaid et al found that MSM who reported higher risk UAI also reported less frequent HIV testing(6). Only 26.7% of men reporting higher risk UAI reported four or more tests in their survey. They were more likely to test in response to a risk event compared to 56.7% men who tested as part of a regular health check.

Barriers to testing highlighted in this study included fear of a positive diagnosis and embarrassment of discussing a sexual history. Other studies have explored the fear associated with testing for HIV(80, 84, 85, 87, 91, 92, 95-99). This was associated with fears about the long-term consequences of living with HIV, loss of quality of life and the need to make changes to their lifestyle and sexual behaviour(78, 87, 91, 96).

Studies also report that motivating factors for HIV testing include triggers such as higher risk sexual experiences(53, 60, 82-86), peer encouragement(85, 86), media campaigns(85) or advice from health service providers, the uncertainty of unknown HIV status and symptoms(296). Several of these factors were highlighted in the study in this thesis.

This study found several service related facilitators to testing, such as short waiting times, weekend and evening opening and short distance to clinic. In a qualitative systematic review of testing preference, services that included community based, non-judgemental, gay-positive service providers and those

that offered a high degree of confidentiality were preferred(78). There was less emphasis placed on access to services. The study in this thesis did not find these factors to be prominent themes. This may have been because we sampled from a sexual health clinic, meaning that the sample was biased towards testing in a clinic rather than community setting. A non-judgemental, gay positive, confidential service may have been viewed as a given since the clinic has a large MSM population and so was not highlighted by participants. Other studies have highlighted similar service-related barriers to testing found in this study. These include inconvenience of location and availability of testing facilities(88, 89) and use of non-rapid HIV testing(101).

Self-sampling was described as overcoming some of these service-related barriers to testing by participants in this survey. However, there was conflict between the convenience of self-sampling and concerns about not being able to access medical advice and health promotion. In general respondents wanted to access a clinic if they had symptoms. Similar findings have also been demonstrated in surveys and a qualitative study of MSM about self-sampling, which cite advantages of convenience, accessibility, confidentiality, privacy and anonymity and concerns of lack of immediate professional support(250, 297, 298).

An additional concern that was not expressed by participants in our study was uncertainty about accuracy(250, 299). This may have been because of the wider availability and marketing of self-sampling at the time of our study compared to previous studies.

Recent advances in HIV prevention that were not highlighted in this study may drive testing in the future. For example, the availability of pre-exposure prophylaxis (PrEP)(300), evidence for the effectiveness of early antiretroviral treatment(301) and awareness about increased HIV risk with use of Chemsex drugs(302) may act as drivers to early and frequent HIV testing.

Reasons for testing frequency have been categorized according to testing frequency and behaviours(54). These include maintenance testers, risk-based testers, convenience testers and test avoiders, as discussed in chapter 2. The respondents in the study in this thesis fell into the category of

maintenance and risk based testers. Respondents only identified with test avoiders at the start of their testing history. A study by Flowers et al also found that fear of positive test was associated with not testing and weaker perceptions of social norms(89).

Testing for routine self-care and responsibility to others was a stronger theme among men reporting UAI in our study, which would fit with the category of 'maintenance testers'. This may be due to a difference in risk perception with men reporting UAI perceiving themselves to be at higher risk of STIs and so not influenced as highly by a change in sexual risk, or because frequent testing may be more socially acceptable among men engaging in UAI. However MSM taking part in the in-depth interviews may have been highly motivated to maintain their health resulting in selection bias. Other studies have found that men reporting UAI test less frequently than men who have multiple partners or have engaged in behavioural interventions(74).

The difference in symptoms driving testing behaviour between men reporting UAI compared to those reporting no UAI may be associated with the greater risk of STIs among men who report unprotected anal intercourse(74).

A study of SMS in South Africa to increase HIV testing found that there was a threshold to the impact of SMS reminders sent in a year, with little additional yield over three SMS(303).

Reminders

The study in this thesis demonstrated that several factors needed to be present to allow reminders to influence intention to test. The reminder had to be confidential. Concerns around confidentiality of SMS reminders has been documented in a literature review by Kannisto et al. They found that respondents were concerned about loss of mobile phones, other people reading messages or the SMS message being sent to someone else incorrectly(115, 304, 305).

In this study, the reminder needed to be convenient to receive, access and act upon. This has been documented in other studies, such as a qualitative study of the use of SMS for smoking cessation support for pregnant smokers(306).

Texting was regarded as highly convenient, resulted in attention to messages but was offset at times by the value of the text being short lived. The value of the SMS could be increased by personalising it- a comment that was made by some participants in our study. A systematic review of periodic prompts or reminders in healthcare demonstrated that prompts were most beneficial when they were personalised(307). It is well established that tailored health messages are more effective at changing health behaviours(308, 309).

Having control in accessing and acting upon a reminder was a theme highlighted in our study. This has been demonstrated in a survey of the use of SMS in smoking cessation. Where the participant did not have control over the SMS received, it was seen as an annoyance or a 'nagging reminder' to stop smoking and suggested negative feelings towards the reminder(310).

Studies of consumers' responses to SMS advertisements have shown that consumers' perceived behavioural control can affect their attitude towards SMS advertisements both negatively and positively. Trust interplays with behavioural control, such that the higher the perceived control, the less trust is required for SMS marketing(311).

However, few studies have explicitly described the theoretical constructs behind the interventions they are using. It is therefore difficult to compare this study's conceptual model with other studies(114).

7.5.4   Limitations

There were several limitations to this study. Firstly, only two in-depth interview participants stated in the survey that they did not intend to retest if sent a reminder. The selection matrix could not be followed as a large number of potential participants were either uncontactable or did not give consent to interview. Participants who consented to being interviewed may have had high 'health maintenance' behaviours, demonstrating a high level of responsibility for their own heath(60). This may have made them more likely to engage in the interviews. This may have resulted in selection bias. However, the interviews were conducted to ensure that there was breadth and depth of data. Several themes were explored to saturation.

The interviews were conducted before data were available on actual retesting/reattendance. It would have been interesting to expand the selection criteria to include this parameter in the selection matrix. However, the interviews explored the nuanced reasons behind intention to reattend on receipt of a reminder. These findings provided insight into why the attitudes explored in the questionnaire survey may not have directly influenced intended and documented reattendance.

Finally, the in-depth interviews were coded by one interviewer. Using two or more researchers to code the interviews increases reliability and validity; however, this was not possible due to financial considerations. Other methods that could have been used included checking intercoder agreement on a subset of the transcript, but this was also limited by financial considerations. Where only one coder is used, there are concerns about stability (the coder's use of codes may change over time), accuracy and lack of reproducibility (use of different coders who code the data the same way increases reliability). In this study, reliability was increased by using simple codes(312).

7.6 Conclusion

The in-depth interviews highlight key themes that may influence HIV/STI testing behaviour that have also been discussed in other literature. This includes responsibility to others, access and wanting to achieve a diagnosis for symptoms.

The effect of these themes on testing behaviour in the context of reminders can be explained to some extent by the conceptual model presented above. A positive attitude to testing behaviour, positive social norms and perceived behavioural control about testing need to be present for a reminder to have a positive influence on testing behaviour and intention to test.

Respondents who were unlikely to return if sent a reminder were concerned about confidentiality and stigmatisation. However, control was an important theme for them also, and they often had their own reminder system in place.

Several respondents preferred to have a health education message accompanying the reminder, which may influence attitude to their testing.

Of note however, only two of those interviewed were not intending to reattend. Therefore not all the themes particular to this group that did not intend to reattend may have emerged. In spite of this, the study gave valuable insights into the results found in the quantitative questionnaire survey.

The next chapter draws together the findings of the systematic literature review, quantitative analysis and qualitative analysis to develop and understand the findings and their implications for service development.

Chapter 8   Discussion

8.1 Introduction

The programme of work set out to explore the drivers and barriers to active recall among men who have sex with men (MSM).

The overall aim of the study was to understand what factors encourage or discourage MSM from engaging with the active recall programme and what are the preferred modes and frequency of active recall for HIV and STI testing.

Specific objectives of the study were:

- to determine whether the published literature provides evidence for the effectiveness of active recall
- to assess whether an active recall intervention for HIV negative/unknown HIV status MSM using SMS reminders increases reattendance rates
- to determine the intention of HIV-negative/unknown HIV status MSM to reattend/re-test for HIV/STIs if they were to receive an active recall reminder, reminder preference and the facilitators and barriers to engagement with active recall for HIV/STIs
- to determine what are the drivers and barriers to HIV testing, testing frequency and active recall reminders; how and why they influence intention to reattend, and what are the contextual factors that influence these drivers and barriers

This final chapter considers the significance of the findings of the programme of work in relation to existing literature. It then discusses the implications of the findings for both future research and service delivery. Finally some of the limitations of the findings are discussed.

8.2 Summary of findings

<u>Effectiveness of active recall interventions in increasing reattendance rates</u>

The findings of this programme of studies suggests that active recall interventions in general are associated with an increase in re-testing rates for HIV/STIs, as demonstrated by the meta-analysis in chapter 4. There is some suggestion from the systematic literature review that SMS reminders are associated with higher reattendance/retesting rates compared to other forms of active reminders. However, the evidence was limited by the heterogeneity of studies.

The results of the service evaluation of SMS reminders reported in chapter 5 were not able to demonstrate an increase in reattendance rates for HIV/STI screening among MSM who reported UAI in the past three months. Furthermore, uptake of reminders was relatively low; 64% of eligible patients declined to receive an SMS reminder.

However, there were several limitations to the analysis. Firstly, the reattendance rate in the control group was high, possibly due to health promotion activities that might have increased reattendance/re-testing rate regardless of exposure to the SMS reminder.

A major limitation to the service evaluation was the non-randomised controlled design that was used. This design was used as randomisation was not feasible; an SMS recall intervention was already in place for MSM diagnosed with an acute bacterial STI and a service development to extend this to all MSM reporting UAI was due to be implemented by the clinic management. Since patients were not randomly allocated to the intervention or control groups, confounders may have modified the effect of the intervention.

The programme of studies demonstrated that the effectiveness of active recall reminders, including SMS reminders such as that used in the service development, is likely to be influenced by multiple factors that were explored through the survey in chapter 6 and in-depth interviews in chapter 7.

Facilitators and barriers to active recall reminders

To explore the reasons why and in which circumstances active recall reminders might increase reattendance rates, the survey in chapter 6 and in-depth interviews in chapter 7 explored the factors associated with, attitudes to, and acceptability of active recall. Preferred modality and frequency of active recall were also explored.

In the survey in chapter 6, a high proportion of survey respondents (93%) reported an intention to reattend if they received a reminder. Despite this, the efficacy of reminders in increasing reattendance rates was relatively low. In the survey group, only one third of reminder recipients reattended, despite all reporting an intention to reattend. In the service evaluation, 45% of SMS recipients reattended.

Uptake of reminders was low. Although three quarters of survey respondents stated that they would prefer to receive a SMS reminder, only 67 survey respondents received a SMS reminder in practice despite 132 reporting UAI with a casual male partner in the past three months and 98 reporting UAI with a regular male partner. However, only 108 (26%) of survey respondents could be matched to the clinic database; therefore the uptake of SMS reminder among survey respondents may not be representative of the clinic attending population. Furthermore, the survey may not accurately reflect the numbers of survey respondents who were eligible for a SMS reminder, due to reporting bias for example.

This low uptake was also seen in the service evaluation in chapter 5, in which 36% of eligible MSM consented to receiving a SMS reminder. This may suggest that active recall reminders are acceptable in general to MSM, but not in the format offered in clinic. It may suggest that MSM find the thought of active recall reminders acceptable in principle, but do not take up the offer suggesting a disconnect between intention and action. The survey may have been subject to response bias with respondents stating that they would find a reminder acceptable as they felt that this was the answer that the researcher wanted.

There were several attitudes associated with increased intention to reattend if sent a reminder, which have been discussed in chapter 6. These included preferring SMS reminders, liking being reminded to check health status, not being concerned about the confidentiality of reminders and preferring to have a reminder to test. However, concern about stigma was a barrier to reattending if sent a reminder. SMS reminders were preferred by the most respondents and preferred testing frequency was every three months.

Although these attitudes were associated with active recall reminders in general, participants may have framed their answers with reference to SMS reminders in the questionnaire survey study, as this is the intervention that was in use in the clinic. Therefore, the attitudes may only be associated with SMS reminders, but not with other reminders. The in-depth interviews highlighted similar attitudes and explored each in more detail. The in-depth interviews were also able to explore attitudes to active recall in general and to each modality separately to distill how attitudes to each type of active recall reminder influences reattendance.

Liking being reminded of one's health status was associated with intention to reattend in the survey. In the in-depth interviews, participants expressed a similar sense of responsibility to oneself through a desire for early diagnosis and access to care or making testing part of routine care regardless of whether they had a risk exposure or symptoms. Having a sense of responsibility towards one's own health has been described as a reason and driver for testing in other studies(78). It draws upon several factors that are linked to how testing is framed within the individuals' life, such as sexual risk perception, responsibility to partners and the influence of a partnership. The 'health maintenance' approach to regular testing, in which testing is seen as routine(60), can be framed as both an attitude to testing and a social norm within the conceptual framework presented in the introduction chapter of this thesis.

Responsibility to others, such as sexual partners, can also be framed within the conceptual framework as a social norm. However, the nature of the relationship with others influences whether this attitude positively or negatively

influences testing behaviour. Responsibility to others can be interpreted as wanting to protect the health of others by not passing on infections, a wider responsibility to the health of the gay community or as a way of proving one's own status in a new relationship(78). Responsibility to the wider gay community has been less commonly discussed in studies of HIV/STI testing. Flowers (91) argues that the advent of technologies such as HIV testing has moved HIV prevention from collective, community focused risk management to an individualised approach in which risk is assessed based on HIV status rather than at the community level. As a result, there is less harnessing of community dynamics to reduce HIV risk(313). Conversely, in a monogamous relationship, mutual trust can act as a barrier to testing. These factors were all highlighted in the in-depth interviews and have been discussed in chapters 6 and 7. Placing this in the context of the conceptual model, a sense of responsibility towards others is weighed up against risk perception and other attitudes to testing, social norms and perceived behavioural control when deciding whether to test for HIV/STIs when a reminder is received.

In the in-depth interviews, being at risk of HIV was mentioned as a driver for testing, for example when first testing for HIV/STIs or in response to a risk event such as a broken condom or UAI. Participants commented on the fear or anxiety associated with testing when they had a heightened risk perception.

Increased risk behaviour was also associated with testing; MSM who reported UAI were more likely to test in response to symptoms. In a literature review of qualitative studies, believing that you were at risk of HIV was identified as both a driver and barrier for testing(78). In some circumstances, believing that you were at risk of HIV was a driver for testing as men wanted to eliminate the uncertainty of not knowing their diagnosis. For others it acted as a barrier as participants did not want to deal with the consequences of a positive diagnosis(78, 85, 87). Drawing upon the conceptual model outlined in the introduction chapter, risk perception can be described as a behavioural attitude. Behavioural attitudes positively associated with testing (e.g. heightened risk perception) need to be present along with social norms and perceived behavioural control to enable reminders to trigger an intention to retest and ultimately the behaviour of retesting.

The attitudes highlighted in the survey and explored in the in-depth interviews go some way to explaining the process by which a reminder might influence testing behaviour. However, two important cross-cutting themes were the importance of personalisation and the dynamic nature of many of the factors that influence testing behaviours. For example, relationship status which influences responsibility to others, changes depending on the type of relationship the person is in at the time of making a decision to test in response to a reminder. The type of relationship status of the individual at the time of receiving a reminder to test will determine risk perception at the time. Therefore, when a person receives a reminder, the relative importance of each of the themes that influence testing behaviour (source identification, early diagnosis, trust and fear/embarrassment) will either be heightened or lessened by the level of perceived risk.

Preferred mode and frequency of active recall reminder

The systematic literature review in chapter 4 did not provide evidence to suggest which of the possible methods of active recall was most effective in increasing reattendance rates. Although it suggested that SMS text reminders might be associated with increased reattendance/re-testing rates, the service evaluation was also unable to confirm this.

The survey suggested that use of an SMS text reminder was associated with increased intention to reattend. Three-monthly recall was preferred by the most respondents. However, the in-depth interviews highlighted that type and frequency of reminder preference is complex in nature and highly dependent on contextual and lifestyle factors.

In general, participants preferred reminders that give them control, are convenient and visually persistent. As previously discussed, reminders associated with health promotion messages were preferred. Preferred frequency depended on sexual risk at the time of receiving the reminder. This personalised approach may explain the disconnect between the high proportion of survey respondents who stated that they would be likely to return for a HIV/STI screen if they received a reminder compared to documented reattendance.

8.3 **Conceptual framework**

The response to an active recall reminder can be framed within the conceptual model described in the introduction chapter, the modified model presented in chapter 7 (in-depth interviews) and drawing upon the results of the survey questionnaire in chapter 6. The final modified framework is presented in figure 13.

A person must first consent to receiving a reminder and intend to reattend. On receiving a reminder, the recipient then makes a decision to reattend. The Theory of Planned Behaviour can be used to inform both steps[10] (figure 13).

The attitudes to testing and testing frequency, social norms around testing behaviour and frequency and perceived behavioural control of testing, combined with perceived behavioural control over a reminder determines whether a recipient consents to receiving a reminder. Perceived behavioural control over testing and reminders then influences actual reattendance.

A person needs to have a positive attitude to testing (e.g. wants to identify the source of their infection, wants to be diagnosed early with an infection). This is counterbalanced by the negative attitudes of fear/embarrassment. If the overall balance of the positive and negative attitudes favours the positive, the participant is more likely to test for HIV/STIs if sent a reminder.

A positive social norm to testing (e.g. medical advice, a sense of responsibility to others, influence of others and not wanting to waste resources) will positively influence testing behaviour.

Furthermore, the person needs to have positive behavioural control of testing by feeling that they will be able to access testing (for example through convenient opening times, confidentiality and ease of accessing testing).

Using the results of the survey questionnaire in chapter 6, a person needs to have a positive attitude to reminders. They need to feel that they like being reminded to check their health status. Furthermore, they need to feel that they have control over a reminder. Therefore, the reminder needs to be

confidential, convenient and provide the participant with control over how to action the reminder (e.g. through an interactive on-line booking system).

If the overall balance of attitude to testing and reminders, social norms of testing and perceived behavioural control over testing and reminders is positive, they are more likely to consent to receiving a reminder and have intention to reattend.

Once a patient who intends to reattend receives a reminder, their actual reattendance is determined by their perceived behavioural control over the reminder and accessing testing. Therefore, the reminder needs to be confidential, convenient, have reminder persistence and provide the recipient with control to access an appointment. This last theme (control to access an appointment) overlaps with perceived behavioural control of testing.

Figure 13: Conceptual framework of the influence of attitudes, social norms and perceived behavioural control on testing behaviours/frequency and its influence on reminders and intention to retest
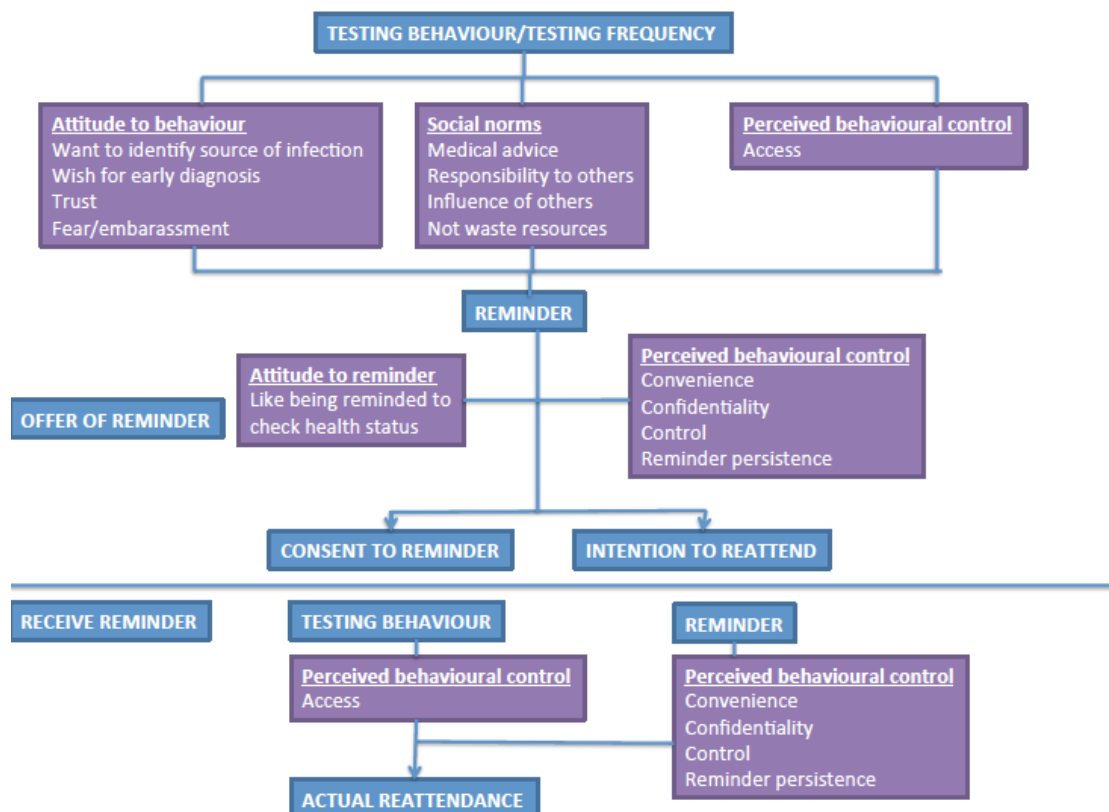
Although the in-depth interviews suggested that this conceptual framework might explain the pathway to intention to reattend and actual reattendance,

the questionnaire survey was only powered to explore the factors associated with intention to reattend. It was unable to differentiate which of the constructs (attitude to testing, social norms, perceived behavioural control) had the greatest influence over intention and documented reattendance due to the limited number of questions exploring each of these constructs individually and the small number of respondents with documented reattendance. Factors not included in this conceptual framework may predict reattendance and other behavioural frameworks discussed in chapter 2 may better predict documented reattendance and should be explored in further work.

A body of research also supports the role of the 'moral norm' in predicting intention. The moral norm is defined as the perceived moral correctness of a behaviour; this is different to the subjective/social norm which refers to perception of social pressure from significant others(293). The influence of the moral norm on retesting/reattendance was not explored in this study.

Therefore, the findings of this study are only able to hypothesise which factors need to be present to enable a reminder to influence intention to retest. A further study would be required to explore and validate the differential effect of attitudes, social norms and perceived behavioural control on intention to reattend and documented reattendance in more depth. Such a study should also explore the influence of moral norms on the variance in intention to retest/reattend.

8.4 New findings

This is one of the first studies of attitudes to active recall reminders and their influence on testing behaviour that is underpinned by a theoretical framework. It suggests that several key attitudes are associated with an increased likelihood of retesting and outlines the nuances that need to be considered when planning a policy of active recall. For example, an SMS message alone, as used in the service evaluation in chapter 5, may not be adequate to increase retesting rates. Active recall interventions may need to take into account the different contexts in which a testing reminder may be received by

an individual and attempt to personalise the intervention to enable intention to retest.

The systematic review in chapter 4 and studies of active recall for HIV/STI testing have used a uniform approach to active recall where all participants receive the same recall intervention. However, this study suggests that a more effective approach to increase retesting rates would be to personalise the recall message and make it as context specific as possible.

8.5 Implications for research

The findings reported in this thesis have a number of implications for future research. This includes lessons for design of future studies, considerations for assessing factors that influence retesting, the need to validate the key attitudes associated with retesting and the need for a cost-effectiveness study to understand whether and which active recall interventions are clinically and cost effective.

Design of future studies and assessing factors associated with retesting

A strength of this programme of research was that it was underpinned by a conceptual framework. As far as possible, the Theory of Planned Behaviour was used as a framework on which to build the survey questions and in-depth interviews. However, there are several other health behaviour models that could have been tested including the Health Belief Model and Trans-theoretical Model. Although chapter 2 argued the reasons for not using these models, it would be useful to assess whether similar conclusions can be drawn using these models of behaviour change.

Future studies should explore in more detail factors associated with documented retesting. A well conducted randomised controlled trial (RCT) of an SMS intervention compared to no intervention would be useful to determine whether SMS interventions are effective in increasing retesting rates and detecting new diagnoses of HIV and STIs as well as exploring factors associated with documented reattendance.

Validation of key attitudes

There were several key attitudes that were identified as being associated with an increased intention to retest. Although none of the attitudes was associated with documented reattendance, the analysis was limited by very small numbers reattending. Therefore, a further longitudinal study with larger numbers reattending would be required to explore the association between attitudes and documented reattendance further.

The in-depth interviews provided insight into the nuanced reasons for how active recall reminders influence intention to reattend. These findings could be used to develop a further questionnaire that determines the attitudes associated with documented reattendance on receipt of a reminder. The questionnaire could also be modified to include assessment of moral norms, which were not included in the survey in this thesis. The questionnaire could then be used to develop a screening tool to identify MSM at risk of not reattending if sent a reminder. The questionnaire would need to be tested for internal consistency of the screening questions, dimensionality, generalisability and, if appropriate, its ability to provide a score that predicts reattendance.

Cost-effectiveness

The systematic literature review identified that active recall interventions can increase retesting rates, but was unable to determine which modality was most effective in increasing retest rates and ascertainment of HIV and STI infections. The review suggested that SMS interventions might be the most effective at increasing reattendance/retesting rates. However, several of the studies in the review involved complex interventions that included behavioural interventions and health promotion that could have contributed to increases in retesting rates.

Taking into account the findings of the survey and in-depth interviews, the SMS reminder should include a personalised health promotion message, be risk specific and be linked to access to services through e.g. an online booking system.

Finally, if it proves effective, it will be important to determine whether such an intervention is also cost-effective. SMS interventions are cheap; however, using a personalised approach will increase costs. A model of the impact of active recall on HIV and STI testing rates and clinical outcomes could be built using the data from RCTs of active recall interventions. Such a model would make assumptions about testing uptake and frequency in response to different recall interventions (e.g. SMS vs email, and personalised vs uniform) for different risk groups of MSM using data from RCTs of active recall interventions.

The modelling data could inform a cost-effectiveness study to determine cost per QALY of active recall interventions. A cost-effectiveness study would require data on NHS service costs for active recall interventions, the costs of managing early vs late diagnoses of HIV and STIs and quality of life of early vs late HIV and STI diagnoses.

8.6 Implications for service delivery

Recent guidance from the British Association for Sexual Health and HIV (BASHH) recommends use of recall strategies for MSM diagnosed with an STI(3). The systematic literature review in chapter 4 suggests that there is benefit of active recall in increasing reattendance/retesting rates overall. However, the findings of the programme of work has several further implications for health policy and service. These include implications for the type of recall strategy used, patient pathways and public health messages about retesting.

Type of recall strategy

Although the BASHH guidance on retesting for STIs among MSM diagnosed with an STI suggests using recall strategies such as SMS(3), the results of the systematic literature review were unable to recommend any one modality of recall strategy over another due to the heterogeneity of studies. Furthermore, the service evaluation (chapter 5) was unable to conclusively demonstrate benefit of SMS in increasing reattendance/retesting rates. Although the

survey and in-depth interviews suggested that SMS recall could be acceptable to MSM, other modalities such as email were also perceived as being acceptable.

Therefore, before implementing a service policy, it is important to acknowledge that more evidence is required about which type of recall reminder is most effective in increasing reattendance/retest rates.

The studies included in the systematic literature review assessed recall at different time intervals and for different indications (e.g. recent STI, high sexual risk) and was not able to determine which time interval and indication is associated with benefit in terms of reattendance/retest. The in-depth interviews suggested that the time interval and indication that would increase the intention to retest varied depending on sexual risk.

Patient pathway

A major theme in the in-depth interviews was the need to streamline the patient pathway and improve access to services through expanded opening hours and access to innovative testing strategies such as self sampling. Using lean principles(283) redundancy in the pathway, such as having to phone to make an appointment for testing, can be eliminated.

Examples of ways in which the patient pathway could be made more streamlined is provision of a link in a recall message to an on-line clinic appointment booking system or order system for self-sampling kits. This could remove barriers to retesting and improve perceived behavioural control within the conceptual framework.

A personalised approach which takes into consideration the participant's sexual risk was suggested as an enabler to testing in the in-depth interviews and has been discussed in the literature (307). This could take the form of a personalised text message, or a personalised web page in which the participants can update their sexual risk profile. They could be offered personalised health promotion messages as well as modifying their recall interval and modality of reminder. Use of personalised digital health promotion in sexual health has been encouraged by national policy(314).

<u>Public health messages</u>

The in-depth interviews highlighted that participants prefer to receive health promotion messages as part of their recall reminder. One participant suggested that messages about the risks of unprotected anal intercourse would be useful and would encourage him to engage with recall. Participants were also concerned about not having access to health promotion if accessing self-sampling. Other studies have also found that reminders that include a health promotion element are well received(308, 309). The social norms approach to health promotion uses different methods to correct negative misconceptions and identifies health behaviours that are the norm in a population. Therefore, the use of health promotion messages may increase intention to retest by positively influencing social norms.

Any recall message should aim to include a health promotion message within it. Where self-sampling is offered, provision of health promotion support may overcome some of the concerns about lack of clinical support and may positively influence social norms associated with self-sampling.

8.7 Limitations

In addition to the sub-study specific limitations detailed in each of the chapters, there are a number of limitations in terms of the relevance of findings.

A substantial amount of the literature on reattendance/retest rates comes from outside of the UK with different healthcare systems and testing policies to the UK. This resulted in several of the studies included in the systematic literature review being downgraded due to poor external validity. The results of the service evaluation, survey and in-depth interviews are from one large sexual health clinic and may not be generalisable to other UK healthcare settings. Furthermore, the survey and in-depth interviews were subject to selection and response bias and results may therefore not be generalisable to all MSM. Nevertheless, several overarching lessons for policy and suggestions for research can be drawn from the findings.

The study used a conceptual model to underpin the methodology and analysis. However, the conceptual model requires further development, especially if the attitudes associated with intention to retest are to be used as a screening tool to identify those do not actually retest.

The conceptual model is static, yet testing behaviour is dynamic. The time gap between survey and documented reattendance may have resulted in key constructs in the conceptual model changing. For example, attitudes to testing may have changed during the time between completing the survey and receiving a reminder and reattending. This may be due to changes in sexual risk behaviour, contextual factors or attitudes may have been influenced by completion of the survey itself. For example, some participants in the in-depth interviews commented that they discussed the survey with their friends and their attitude to retesting was influenced by the survey.

An evaluation of a service development was used to assess whether introduction of an SMS reminder would increase reattendance rates. The clinic setting already used text message reminders to recall MSM who were diagnosed with an acute bacterial STI and a service development to extend this to all MSM reporting UAI was due to be implemented by the clinic management; therefore a randomised controlled trial (RCT) was not feasible. The optimal study design would be a RCT of active recall compared to no active recall to determine whether reminders increase retesting/reattendance rates. However, there is a body of literature that suggests that well conducted non-experimental evaluation methods can approximate the findings of randomised control trials and may be used in preference in social settings where an RCT might not be feasible or overly burdensome(315, 316).

The programme of research used a mixed methods approach, which enabled an exploration of drivers and barriers to active recall and how these influence testing behaviour. However, attitudes to active recall were not associated with documented reattendance. The analysis was underpowered due to the small numbers of participants who received a reminder or reattended. However, the in-depth interviews suggested that the relationship between the constructs of the theoretical framework and reattendance is nuanced. Insights from the in-

depth interviews could be used iteratively to inform the development of a modified survey to explore in more depth each of the constructs of the theoretical framework (attitude to testing, social norms and perceived behavioural control) and to understand their relative contribution to the variance in intention to retest.

Finally, although the study attempted to take into account wider social and cultural norms, the longer-term impact of socio-cultural norms on testing behaviour has not been taken into account as changes in socio-cultural norms over time influence testing behaviour. Nonetheless, the study offers some insights into how socio-cultural norms need to be considered in terms of their influence on testing behaviour in response to recall.

8.8 Conclusion

Men who have sex with men (MSM) remain the most at risk group for infection with HIV in England. Current strategies have not succeeded in curtailing the epidemic and over a quarter remain undiagnosed. A successful prevention approach needs to be multi-faceted, using all the tools available in the prevention tool-kit. The use of active recall reminders is one such tool. It relies on targeting those already known to sexual health services, the men who remain at high risk of HIV infection, but who do not test frequently.

This programme of research has shown that active recall can increase reattendance/retesting rates. However, although the literature suggests that SMS reminders might increase reattendance rates, the service evaluation in thesis demonstrated inconclusive results.

Therefore which modality of active recall is most effective in increasing reattendance rates, at which frequency, in response to which risks and whether this translates into clinical and cost benefit remains unknown. Nevertheless, it is clear that any recall intervention needs to be personalised and include a health promotion component to ensure that attitudes to testing, social norms and perceived behavioural control are optimised. This will enable reminders to increase intention to retest and hopefully actual retesting.

Appendices

1. Systematic literature review

1.1 Example search strategy

CINAHL search performed on 25th October 2013

	8.8.1.1.1.1.1.1.1 Search terms	8.8.1.1.1.1.1.1.2 Results
S8	S5 AND S6 AND S7	450
S7	S3 OR S4	577,251
S6	S1 OR S2	67,724
S5	remind* OR recall OR repeat* AND rescreen* OR text OR SMS OR short message service OR mobile OR email OR phone* OR mobile phone OR telephone	54,550
S4	test*	527,094
S3	screen*	83,572
S2	STI OR sexually transmit* infection OR sexually transmit* disease OR chlamydia OR gonorrhea	7,120
S1	HIV	62,415

1.2 Reasons for exclusion

Reasons for study exclusion (N=27)

No active recall (N=5)

Conference abstract (N=4)

Qualitative study (N=3)

Health promotion (N=2)

Reviews (N=2)

No reattendance outcome (N=1)

Rescreening rates (N=1)

Natural history of infection (N=1)

Drivers and barriers to retesting not active recall (N=1)

Factors associated with rescreening (N=1)

Reminder to clinicians (N=1)

Results for HIV (N=1)

News article (N=1)

Overview of prevention (N=1)

Unable to obtain paper (N=1)

Same study as an included paper (N=1)

1.3 Risk of bias tables

Table 17: Summary quality assessment of included studies

	Internal validity	External validity
RCT		
Cook(270)	++	-
Downing(112)	+	+
Gotz(259)	+	-
Sparks(268)	+	-
Xu(269)	+	-
Malotte(171)	+	-
Non-randomised before and after studies		
Burton(260)	+	-
Bourne(168)	+	-
Guy(111)	+	-
Zou(265)	+	-
Paneth-Pollack(271)	+	-
Observational studies		
Gotz(172)	++	-
Harte(77)	+	-
LaMontagne(261)	+	-
Walker(267)	+	-
Bloomfield(272)	+	-

| Cameron(262) | + | - |

Key:

For individual criterion

++   For that particular aspect of the study design, the study has been designed in such a way as to minimise the risk of bias

+   the answer to the question is not clear from the way the study is reported or the study has not addressed all the potential sources of bias for that particular aspect of the study design

-     significant sources of bias may persist

NR   study has not reported how that question should have been considered

NA   not applicable for the given study design under review

For overall external validity/internal validity

++   All or most of the checklist criteria have been fulfilled. Where they have not been fulfilled, the conclusions are very likely to alter

+   some of the checklist criteria have been fulfilled. Where they have not been fulfilled or not adequately described, the conclusions are unlikely to alter

-     few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter

Table 18: Detailed methodological quality assessment

INTERVENTIONAL STUDIES										
		Downing, STIJ 2013(112)	Malotte STD 2004(171)	Gotz BMC Infect Dis 2013(259)	Sparks STD 2004(268)	Xu Obstetr Gynacol 2011(269)	Cook STIJ 2007(270)	Bourne STIJ 2011(168)	Zou PLoS One 2013(265)	Guy STIJ 2013(111)
	Study type	RCT	RCT	RCT	RCT	RCT	RCT	Non-randomised before and after	Non-randomised before and after	Non-randomised before and after
POPULATION	Source population	+	+	+	+	+	+	+	+	+
	Representativeness	+	+	+	+	+	+	+	+	+
	Method of selection of participants	+	+	++	+	+	++	+	-	+
ALLOCATION	Minimisation of selection bias	++	++	++	++	++	++	-	-	-
	Description of interventions and comparisons	++	+	+	++	++	+	++	++	++
	Allocation concealment	+	++	++	+	++	++	N/A	N/A	N/A
	Blinding	++	+	+	+	-	+	-	-	-
	Exposure	-	++	+	++	+	++	+	+	+
	Contamination	++	++	++	++	++	++	++	++	++
	Similar intervention in both groups	++	+	++	+	+	++	++	++	++
	Loss to follow up	++	++	++	++	+	++	++	++	++
	UK setting	+	+	+	+	+	+	+	+	+

	UK practice	++	+/-	+	++	+	-	+	-	+
OUTCOMES	Reliability	++	++	++	++	++	++	++	++	++
	Completeness	++	++	++	++	-	++	++	++	++
	Importance of outcomes	+	+	+	+	+	+	+	+	+
	Relevance of outcomes	++	++	++	++	++	++	++	++	++
	Similarity of follow up times	++	++	++	++	++	++	++	++	++
	Relevance of follow up times	++	++	++	++	+	+	++	++	++
ANALYSES	Confounding	++	+	+	+	++	++	++	++	++
	ITT	++	++	++	++	+	++	++	-	++
	Power	++	+	+	-	-	++	+	+	+
	Effect estimates	++	++	++	++	++	++	++	++	++
	Analytic methods	+	++	++	++	++	++	++	++	++
	Precision	+	+	++	-	-	++	++	++	++
SUMMARY	Internal validity	+	+	+	+	+	++	+	+	+
	External validity	+	-	-	-	-	-	-	-	-

OBSERVATIONAL STUDIES

		Harte STIJ 2010(77)	Bloomfield STIJ 2003(272)	Gotz STIJ 2013(172)	LaMontagne STIJ 2007(261)	Walker PLoS One 2012(267)	Cameron Human Reprod 2009(262)
POPULATION	Source population	+	+	+	+	+	+
	Representativeness	+	+	+	+	+	+
	Method of selection of participants	++	++	++	++	+	+
ALLOCATION	Minimisation of selection bias	+	-	++	++	++	+
	Explanatory variables based on theory	+	-	++	++	-	-
	Low contamination	N/A	N/A	N/A	N/A	N/A	N/A
	Confounders controlled/adjusted	N/A	N/A	N/A	N/A	N/A	N/A
	Applicable to UK setting	++	+	+	+	+	++
OUTCOMES	Reliability	++	+	++	++	++	++
	Completeness	++	++	++	++	++	++
	Importance of outcomes	+	+	+	+	+	+
	Similarity of follow up times	N/A	N/A	N/A	NA	N/A	N/A
	Relevance of follow up times	++	-	+	++	++	++
	Low withdrawal rate	++	++	++	++	++	++
ANALYSES	Power	-	-	-	++	++	++
	Multiple exlpanatory variables	+	-	++	++	+	+
	Analytic methods and adjust for confounders	++	++	++	++	++	++

	Precision	++	++	++	++	++	++
SUMMARY	Internal validity	+	+	++	+	+	+
	External validity	-	-	-	-	-	-

1.4 Clinical outcomes

Table 19: Clinical outcome for randomised controlled trials

STUDY	Number of new infection at retest (number of infections/number who retest)				Number of new infections at recall (number of infections/number who are recalled)		
	Clinical outcome	Intervention group	Control group	Crude OR (95% CI), statistical finding [2]	Intervention group	Control group	Crude OR (95% CI), statistical finding[2]
		n/N	n/N		n/N	n/N	
Type of intervention: SMS							
Downing et al STIJ 2013(112)[1]	Chlamydia infection at retest	2/8 (25%)	0/2 (0%)	N/A	2/30 (7%)	0/32 (0%)	N/A
Type of intervention: Phone call/ letter							
Malotte et al STD 2004 USA(171)	Chlamydia infection at second re-test (i.e. 4.5 months after baseline)	Not available for all patients	N/A	N/A	N/A	N/A	N/A
Type of intervention: send home sampling kit							

Gotz et al BMC Infect Dis 2013(259)[1]	Chlamydia infection at retest	8/50 (16%)	5/25 (20%)	OR= 0.8 95% CI (0.2, 2.6)	8/109 (7%)	5/107 (5%)	Calc OR= 1.6 (Calc 95% CI 0.4, 6.5)
Sparks et al STD 2004(268)	Chlamydia or gonorrhoea infection at retest	Not available for all patients	N/A	N/A	N/A	N/A	N/A
Xu et al Obstetr Gynacol 2011(269)[1]	Chlamydia infection at retest	STI clinic recruits: 17/122 (13.9% ; 95% CI 8.3-21.4) FP recruits: 12/93 (12.9% ; 95% CI 6.9-21.5)	STI clinic recruits: 19/98 (19.4% ; 95% CI 8.3-21.4) FP recruits: 8/55 (14.6% ; 95% CI 6.5-26.7)	STI clinic group: calc OR= 0.7 (calc 95% CI 0.3, 1.5) FP group: calc OR= 0.9 (calc 95% CI 0.3, 2.6)	STI clinic recruits: 17/408 (4.2%) FP recruits: 12/196 (6.1%)	STI clinic recruits: 19/403 (4.7%) FP recruits: 8/208 (3.8%)	STI clinic group: calc OR= 0.9 (calc 95% CI 0.4, 1.8) FP group: calc OR= 1.6 (calc 95% CI 0.6, 4.7)
Cook et al STIJ 2007(270)	STDs	20.4 per 100 py	24.1 per 100 py	N/A	N/A	N/A	N/A

1. Where number of new infections at retest is not provided by the paper, it has been calculated
2. OR and 95% CI is calculated where not provided in the paper and is specified as 'calc OR' or 'calc 95% CI'

Table 20: Clinical outcome for observational studies

STUDY	Number of new infections at retest (number of infections/number who retest)				Number of new infections at recall (number of infections/number who are recalled)		
	Clinical outcome	Intervention group	Control group	Crude OR (95% CI), statistical finding	Intervention group	Control group	Crude OR (95% CI), statistical finding
		n/N	n/N		n/N	n/N	
Type of intervention: SMS							
Bourne et al STIJ 2011(168)	Not reported	N/A	N/A	N/A	N/A	N/A	N/A
Zou et al PLoS One 2013(265)	Bacterial STI (chlamydia, gonorrhoea, syphilis), HIV	pharyngeal Gc: 16/885 (1.8%) Rectal Gc: 24/885 (2.7%) Urethral Ct: 26/885 (2.9%) Rectal Ct: 51/885 (5.8%) Early STS: 25/885	1. Concurrent control group: Pharyngeal Gc: 13/978 (1.3%) Rectal Gc: 12/978 (1.2%) Urethral Ct: 14/978 (1.4%)	1. Concurrent control: Pharyngeal Gc: calc OR= 1.4 (calc 95% CI 0.6, 3.1) Rectal Gc: calc OR=2.2 (calc 95% CI 1.1, 5.0) Urethral Ct: calc OR=2.1 (calc 95% CI 1.0, 4.3)	pharyngeal Gc: 16/997 (1.6%) Rectal Gc: 24/997 (2.4%) Urethral Ct: 26/997 (2.6%) Rectal Ct: 51/997 (5.1%) Early STS: 25/997	1. Concurrent control group: Pharyngeal Gc: 13/1382 (1.3%) Rectal Gc: 12/1382 (1.2%) Urethral Ct: 14/1382 (1.4%) Rectal Ct:	1. Concurrent control: Pharyngeal Gc: calc OR= 1.7 (calc 95% CI 0.8, 3.9) Rectal Gc: calc OR=2.8 (calc 95% CI 1.3,

		(2.8%) Early latent STS: 12/885 (1.4%) HIV: 7/885 (0.8%)	Rectal Ct: 27/978 (2.8%) Early STS: 15/978 (1.5%) Early latent STS: 4/978 (0.4%) HIV: 3/978 (0.3%) 2. Historic control group: Pharyngeal Gc: 11/1454 (0.8%) Rectal Gc: 14/1454 (1.0%) Urethral Ct: 14/1454 (1.0%) Rectal Ct: 22/1454 (1.5%)	Rectal Ct: calc OR=2.2 (calc 95% CI 1.3, 3.6) Early STS: calc OR=1.9 (calc 95% CI 0.9, 3.8) Early latent STS: calc OR=3.3 (calc 95% CI 1.0, 14.3) HIV: calc OR=2.6 (calc 95% CI 0.6, 15.7) 2. Historical control: Pharyngeal GC: calc OR= 2.4 (calc 95% CI 1.0, 5.8) Rectal Gc: calc OR=2.9 (calc 95% CI 1.4, 6.0) Urethral Ct:calc OR=3.1 (calc 95% CI 1.6, 6.5) Rectal Ct: calc OR=4.0 (calc 95% CI 2.3, 6.9) Early STS: calc OR=1.4	(2.5%) Early latent STS: 12/997 (1.2%) HIV: 7/997 (0.7%)	27/1382 (2.8%) Early STS: 15/1382 (1.5%) Early latent STS: 4/1382 (0.4%) HIV: 3/1382 (0.3%) 2. Historical control group: Pharyngeal Gc: 11/1800 (0.7%) Rectal Gc: 14/1800 (0.7%) Urethral Ct: 14/1800 (0.8%) Rectal Ct: 22/1800 (1.5%) Early STS: 30/1800 (0.8%) Early latent STS: 15/1800 (0.2%) HIV: 10/1800 (0.2%)	6.2) Urethral Ct: calc OR=2.6 (calc 95% CI 1.3, 5.4) Rectal Ct:calc OR=2.7 (calc 95% CI 1.7, 4.5) Early STS: calc OR=2.4 (calc 95% CI 1.2, 4.8) Early latent STS: calc OR=4.2 (calc 95% CI 1.3, 17.9) HIV:calc OR=3.2 (calc 95% CI 0.7, 19.5) 2. Historical control: Pharyngeal GC

| | | | Early STS: 30/1454 (2.1%) Early latent STS: 15/1454 (1.0%) HIV: 10/1454 (0.7%) | (calc 95% CI 0.8, 2.4) Early latent STS: calc OR=1.3 (calc 95% CI 0.6, 3.0) HIV: calc OR=1.2 (calc 95% CI 0.4, 3.4) | | | calc OR= 2.7 (calc 95% CI 1.1, 6.3) Rectal Gc: calc OR=3.1 (calc 95% CI 1.6, 6.6) Urethral Ct:calc OR=3.4 (calc 95% CI 1.7, 7.1) Rectal Ct: calc OR=4.4 (calc 95% CI 2.6, 7.6) Early STS: calc OR=1.5 (calc 95% CI 0.8, 2.7) Early latent STS: calc OR=1.4 (calc 95% CI 0.6, 3.3) HIV: calc OR=1.3 |

							(calc 95% CI 0.4, 3.7)
Burton et al STIJ 2013(260)	All STIs	15/91 (17%)	13/90 (14%)	Calc OR = 1.2 (calc 95% CI 0.5, 2.9)	15/273 (5.5%)	13/266 (4.90%)	Calc OR= 1.1 (calc 95% CI 0.5, 2.6)
Guy et al STIJ 2013(111)	Not reported	N/A	N/A	N/A	N/A	N/A	N/A
Type of intervention: Phone							
Harte et al STIJ 2011(77)	Bacterial STI (chlamydia, gonorrhoea, syphilis, LGV), HIV	Acute bacterial STI: 15/206 (7.3%) HIV:5/168 (3.0%)	N/A	N/A	N/A	N/A	N/A
Type of intervention: Postcard/letter							
Paneth-Pollack et al STD 2010(271)	Chlamydia and gonorrhoea infection at	22/179 (12.30%)	1. Non-intervention group: 58/288 (20.1%)	1. Non- intervention group: calc OR= 0.6 (calc 95% CI 0.3, 1.0)	22/1267 (1.70%)	1. Non-intervention group: 58/3861 (1.5%)	1. Non-intervention group: calc OR= 1.1

retest		2. Historic control: 24/94 (25.5%)	2. Pre-intervention group: calculated OR= 0.4 (calc 95% CI 0.2, 0.8)		2. Historic control: 24/1092 (2.2%)	(calc 95% CI 0.7, 1.9) 2. Pre-intervention group: calculated OR= 0.8 (calc 95% CI 0.4, 1.5)	

Type of intervention: send home sampling kit

Bloomfield et al STIJ 2003(272)	Chlamydia infection at retest	2/63 (3.2%)	N/A	N/A	2/399 (0.50%)	N/A	N/A
Gotz et al STIJ 2013(172)	Chlamydia reinfection	242/2756 (8.8%)	n/a	n/a			
LaMontagne et al STIJ 2007(261)	Chlamydia infection at retest	GP recruits: 29.9 (95% CI 19.7-45.4) per 100py FP recruits: 22.3	N/A	N/A	N/A	N/A	N/A

		(95% CI 15.6-31.8) per 100 py					
Walker et al PLoS One 2012(267)	Chlamydia infection at retest	3 months: 7/40 (18%) 6 months: 25/884 (3%) 12 months: 15/874 (2%)	N/A	N/A	N/A	N/A	N/A
Cameron et al Hum Reprod 2009(262)	Chlamydia infection at retest	32/215 (15%)	N/A	N/A	32/330 (9.70%)	N/A	N/A

1.5 Funnel plots

Figure 14: Funnel plot for randomised controlled trials

Funnel plot with pseudo 95% confidence limits
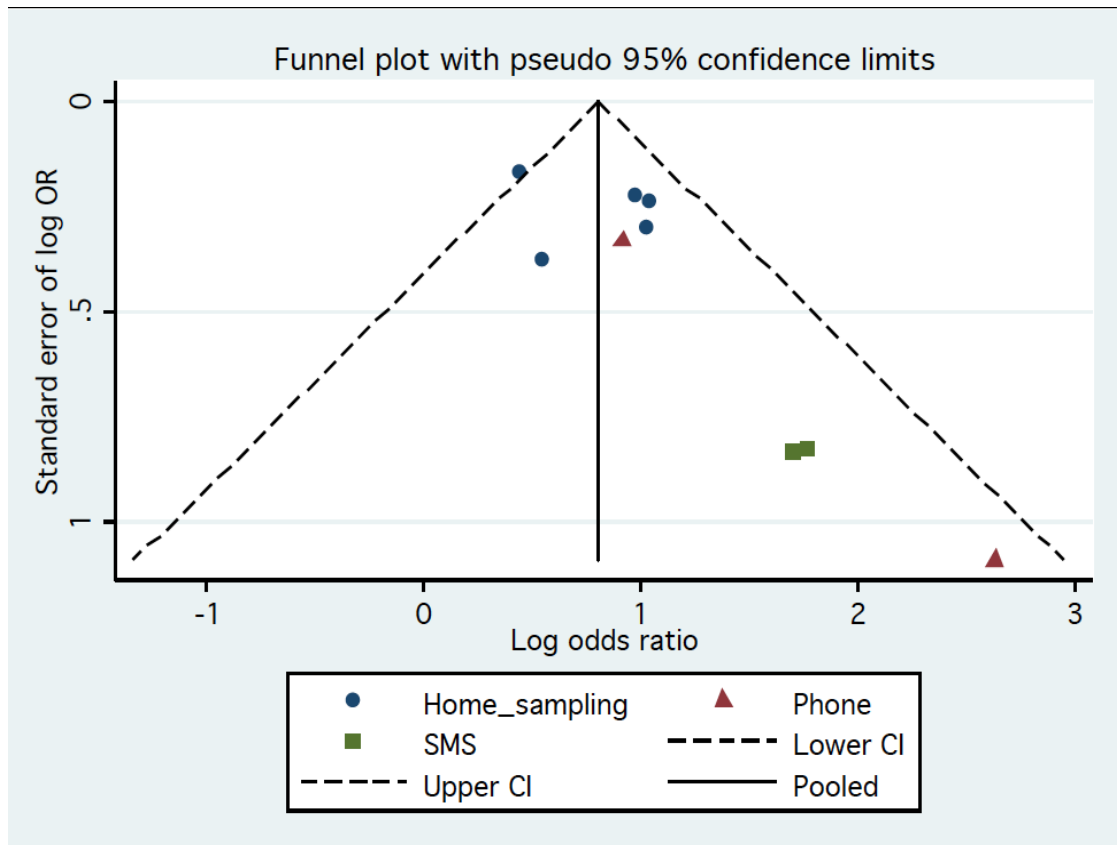
Figure 15: Funnel plot of observational studies

Funnel plot with pseudo 95% confidence limits
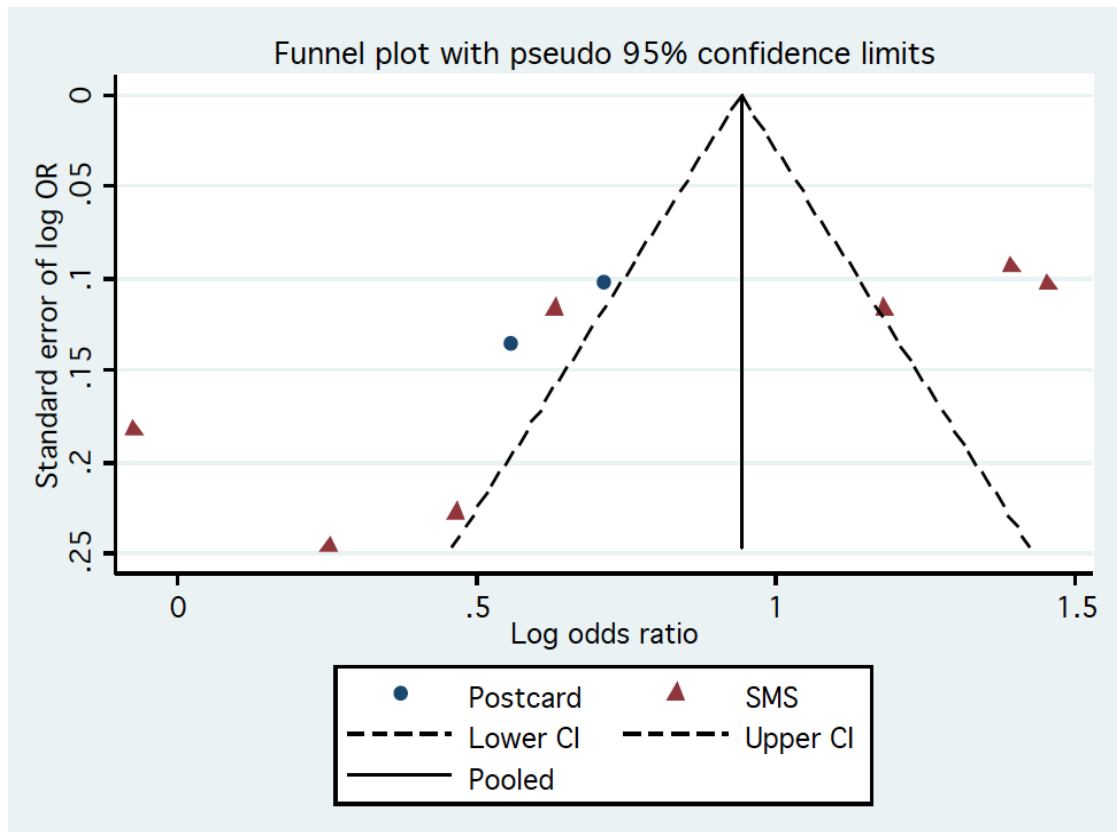
2. Service development

2.1 Patient information sheet for text message reminders

Figure 16: Patient information leaflet for the service development of introduction of SMS text reminders for men who have sex with men who report unprotected anal sex with a casual male partner in the past three months

HIV testing:
Active Recall Pilot
Information for patients

Central and North West London **NHS**
NHS Foundation Trust

Camden Provider Services
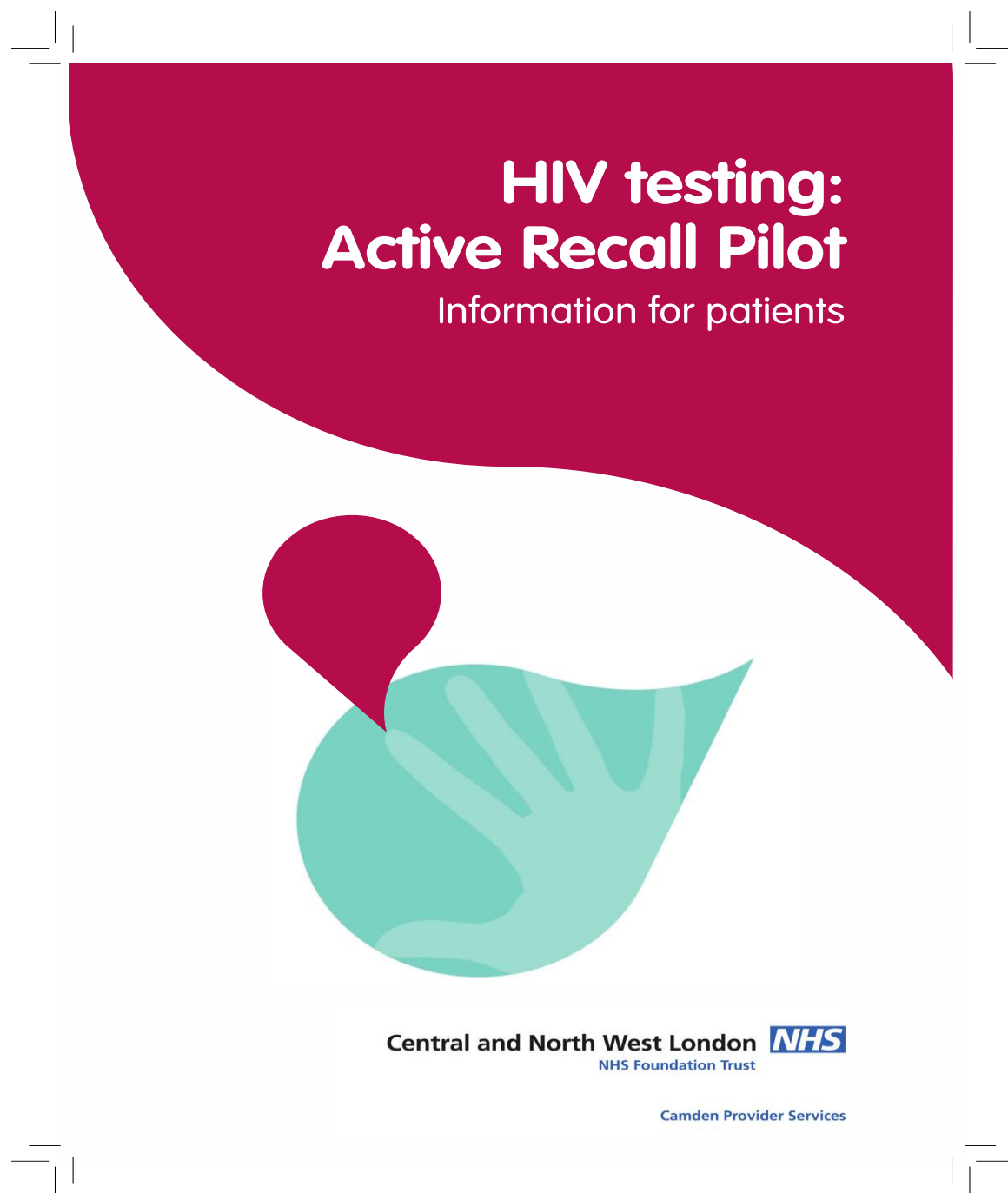
About This Pilot:

The most recent figures show that gay and other men who have sex with men (MSM) are still among the groups most affected by HIV.

The most common way for gay and other MSM to become infected with HIV is through unprotected anal sex (sex without a condom).

At Mortimer Market Centre and The Archway Centre, we are piloting Active Recall for repeat HIV testing of gay and other MSM who have had unprotected anal sex with one or more male partners within the last three months.

If you report having had unprotected anal sex with one or more male partners within the last three months, you will be invited to take part in the Active Recall Pilot. Your clinician will ask you if you are happy for us to send you a text message in three months' time, reminding you to come back for a repeat HIV test and a sexual health screen.

If you are diagnosed with a sexually transmitted infection (other than HIV) and you have agreed to take part in the Pilot, you may receive more than one reminder text message.

If you agree to receive the reminder messages, you can change your mind and opt out at any time. Just tell your clinician or ring our appointments line on 020 3317 5100.

Frequently Asked Questions:

Why are you running this pilot?

We are running this pilot project to find out whether this idea of 'active recall' is acceptable to gay and other MSM who report risk-taking behaviours. We hope that men will accept and get tested every three months, and that this will result in fewer new HIV infections.

How will more frequent testing help prevent new HIV infections?

Many research studies have shown that:

- HIV-positive people are most infectious to others soon after they are first infected;

- Once people know they are HIV-positive, the majority take great care to avoid passing the infection on to others; and

- Once people are taking HIV treatments, they become very much less infectious to others.

How will more frequent HIV testing help me?

If you have been infected with HIV, the sooner you know, the better. This is because:

- doctors will monitor your health and prescribe HIV treatment drugs for you at the right time, before HIV has had a chance to damage your health; and

- HIV-positive people who get treated at the right time have a very good chance of living a normal lifespan in good health.

Did You Know?

You can walk in to our clinics at Mortimer Market Centre and The Archway Centre without an appointment and have a rapid HIV test. The result will be available within minutes.

Walk-in rapid HIV tests are available at these times:

Mortimer Market Centre

Mon	9am — 6pm
Tues	9am — 7pm
Wed	1pm — 6pm
Thur	9am — 6pm
Fri	9am — 3pm

www.mortimermarket.com

The Archway Centre

Mon	9am — 6:15pm
Tues	9am — 6:15pm
Wed	1:30pm — 6:15pm
Thur	9am — 7:15pm
Fri	9am — 3:15pm

www.archwaycentre.com

2.2 Sample text message for service development

It has been three months since your last screen. Call Mortimer Market Centre on 020 3317 5100 for a free and confidential sexual health screen. We also offer a walk-in point of care HIV testing service.

2.3 Comparison of baseline characteristics for reattenders vs non-reattenders

Table 21: Baseline comparison of reattenders vs non-reattenders after semi-automation

	All patients	%	Reattenders	%	Non-reattenders	%	p value comparing reattenders vs non-reattenders*
Number	999		451		548		
Age Mean Range Median	34.7 16-76 33		35.2 17-75 34		34.5 16-76 32		0.080
Clinical tests HIV test today	774	81.70%	323	74.94%	451	87.40%	**<0.001**
Consent to recall	364	36.00%	163	36.14%	201	36.68%	0.861
Rettend overall	451	45.00%	n/a		n/a		
Reattend in consent to recall group	163	16.32%	n/a		n/a		

*Fisher's exact where cells contain <5 observations. Chi2 test where >=5 observations. Ages transformed to 5 year band categories

2.4 Comparison of MSM consenting to recall compared to MSM not consenting to recall

Table 22: Comparison of consent to recall vs no consent to recall at baseline in the post-automation period

	All patients	%	Consent recall	%	Do not consent recall	%	P value comparing consent vs no- consent *
Number	999		364		635		
Age Mean Range Median	34.7 16-76 33		33.5 16-73 31.5		35.4 17-76 34		0.005
Clinical tests HIV test	774	81.70%	318	91.10%	456	76.20%	**<0.001**
Recalled	364	36.00%	n/a		n/a		
Reattend	451	45.00%	163	45%	288	45%	0.861

3. Cognitive interviews

3.1 Cognitive interview patient information sheet

Central and North West London NHS

NHS Foundation Trust

Camden Provider Services

!

PARTICIPANT INFORMATION SHEET

Research Title: Drivers and barriers to active recall for HIV testing of men who have sex with men at high risk of HIV infection in Genitourinary Medicine clinics- cognitive interviews

1. What is the purpose of the study?

We are inviting you to take part in a study to examine what encourages or deters gay or homosexual men from being reminded to have regular tests for HIV and sexually transmitted infections (STIs). We would like your help in telling us whether one of the study methods we intend to use- a questionnaire- is easy to understand.

2. Why have I been invited?

We want to talk to about ten gay or homosexual men, who are attending a sexual health clinic visit. You must be aged over 16, be HIV negative as far as you know and be able to read and write English. You cannot take part if you are HIV positive, have been offered post-exposure prophylaxis on this visit or are taking part in the PROUD study of pre-exposure prophylaxis.

3. What will I have to do?

You will be asked to spend about **30 minutes** talking with the researcher about how easy the questionnaire is to fill out and understand.

You will have the conversation with the researcher in a private clinic room at the Mortimer Market Clinic. The conversation will be audio recorded so that the research team can review your answers. You will have the opportunity to ask any further questions about the study at before the discussion begins and you will be asked to sign a consent form at the start of the discussion.

The questionnaire asks some basic demographic questions, questions about your sexual health, your lifestyle and your views on testing for HIV and STIs and being reminded to have the tests.

4. Will I be paid to take part?

You will receive a high street voucher as a small compensation for your time. You will also be able to claim reasonable travel expenses up to a value of £10. Some refreshments will be provided during the discussion.

5. What will happen if I don't want to carry on with the study?

You do not have to join if you do not want to. If you change your mind during the cognitive interview study you can withdraw at any time with or without giving a reason. If you withdraw from the cognitive interview study, any information that could be linked back to you will be destroyed. However, any information that you have already provided that cannot be linked back to you will be used in the study analysis.

Deciding not to take part in the study will not affect your medical care.

6. What are the possible risks of taking part?

There is no risk to you taking part in this study. If you find that the discussion raises issues that you would like to discuss further, please ask the researcher to arrange for you to speak to one of the investigators.

7. What if something goes wrong?

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the Camden Provider Services but you may have to pay your legal costs. The normal National Health Service complaints mechanism will still be available to you.

8. Will my responses be confidential?

Nobody outside of the research group and clinicians will know that you are taking part in the study.

The questionnaire is pseudo-anonymous- it will have your clinic number and date of birth on it. However, the results you provide on the questionnaire will not be used in the analysis.

For the discussion recordings, anything that could identify you will be removed from the audio recording. You will only be identified by your study number. A specially trained researcher will listen to and analyse all the discussions.
The audio recording will be stored in a secure site in the research office.

Data will be stored in accordance with the Data Protection Act 1998 and NHS Regulations for 3 years, after which time it will be disposed of securely.

The data collected may be used for additional related research after approval from the Research Ethics Committee.

9. What will happen to the results of the research study?

The results of the cognitive interviews will be used to modify the final survey tool. The results will be published in an internal report and in peer reviewed publications. You will not be identified in the results of the study that are published.

10. Who is organizing the study?

This study is being organised by University College London and Public Health England and is sponsored and insured by Camden Provider Services, part of Central and North West London NHS Foundation Trust. The study is funded by the British HIV Association.

11. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Leeds West Research Ethics Committee (ref: 13/YH/0347).

Cognitive!interview!PIS!v0.5!19th!Nov!2013!

12. Who should I talk to if I have more questions?

If you have more questions about any aspect of this study, please contact a member of the research team on 0203 108 2361.

If you have any concerns and wish to complain formally, you can do this by contacting patientsupport.cps@nhs.net.

Thank you for taking the time to read this information sheet and considering the study.

!

3.2 Cognitive interview consent form

Central and North West London NHS
NHS Foundation Trust

Camden Provider Services

Research title: Drivers and barriers to active recall for HIV testing of MSM at high risk of HIV infection in Genitourinary Medicine clinics: cognitive interviews

Patient identification number   ……………………………...

Name of person taking consent   ……………………………...

Contact details of person taking consent …………………………….

PLEASE INITIAL BOXES

1. I confirm that I have read and understand the information sheet dated 19th November 2013 (version 0.5) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that the discussion will be audio recorded and that delegated members of the research team will listen to the tape to either transcribe or analyse the discussion. I give permission for the discussion to be audio recorded and for delegated members of the research team to have access to the audio recording, or transcription of it, and for verbatim quotations to be used in the study reports, but understand that my confidentiality will be maintained.

4. I understand that any of my study notes, including audio or written files of the discussion, may be looked at or listened to by responsible individuals from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records, but understand that my confidentiality will be maintained.

5. I understand that relevant sections of data collected during the study, may be looked at by individuals from the sponsor of the trial (Central and Northwest London NHS Foundation Trust) and responsible persons authorised by the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

6. I understand that the data collected in this study may be used in future studies

7. I agree to take part in the above study.

_____   _____   _____
Name of Participant   Date (dd/mm/yyy)   Signature

_____   _____   _____
Name of Researcher   Date (dd/mm/yyyy)   Signature

_____   _____   _____
Name of person asking for consent   Date (dd/mm/yyyy)   Signature
(if different to the person taking consent)

When completed: 1 for participant; 1 (original) for researcher site file; 1 to be kept in medical notes.

Cognitive interview consent v 0.3 22nd Jan 2014

3.3 Cognitive interview results

Consent

Having read the information above, do you agree to participate in this study?

☐ Yes   ☐No

→Thank you for your time. Please hand this blank questionnaire to clinic reception

---

Objectives

1. To determine whether the participant consents to taking part in the study

---

All participants were able to answer this question without any problems.

Recommendation

- **No need to change this question**

Section A: Eligibility and attendance

<u>Judgement</u>

- Six (75%) of the participants read the introduction paragraph. One participant commented that this paragraph repeated some of what had been said on the first page.

Recommendation

- **Make introduction paragraph to Section A more succinct**

A1. What is your gender?

☐ Male   ☐Female

☐ Transgender (female->male)   →This survey is for men only. If you are not male, please do not complete it and hand it to clinic reception

---

Objectives

> **To ensure that inclusion and exclusion criteria are met regarding gender; this**
>
> **survey is for males or transgender female to male only**

All participants were able to answer this question without any problems.

Recommendation

- **No need to change this question**

A2. Have you ever had sex with a man? By sex, we mean oral or anal sex.

☐ Yes   ☐No

`   → This survey is for men who have had sex with men only. If you have never had sex with a man, please do not complete it and hand it to clinic reception.

> *Objectives*
>
> **To ensure that inclusion and exclusion criteria are met; this survey is for men who have sex with men only**

Cognition

- All participants read the explanation for this question and understood that both anal and oral sex were included in the definition of sex.
- All participants were able to answer this question without any problems

Recommendation

- **No need to change this question**

A3. Are you HIV positive?

☐ No   ☐Yes

`   → This survey is for HIV negative men only. If you are HIV positive, please do not complete it and hand it to clinic reception

<u>Cognition</u>

- All participants commented that they were HIV negative as far as they knew. They acknowledged that they would be having an HIV test at a clinic visit, and would not know the outcome of this test at the time of filling out the survey.
- All participants were able to answer this question without any problems

Recommendation

- **No need to change this question**

A4. Are you attending the clinic today because you have been reminded to return for a HIV and STI screen?

☐ No

☐ Yes → How were you reminded: ☐ By text message

☐ Advised by the clinician on my last visit to return for a HIV and STI test

☐ Other, please specify _____

> *Objectives*
>
> **To determine whether participants have been recalled for a HIV/STI screen and if this recall was part of the active recall programme. Will allow analysis by active recall vs no active recall and will allow us to check against clinical records for the patient to see if the clinician noted that the participant was to be actively recalled.**

<u>Issues with objectives</u>

- Despite the problems with cognition outlined below, all men who had been recalled by text message found this question easy to understand and answered it correctly.

Cognitive: Comprehension

- One participant, who was non-English speaking, did not know what the term STI stood for and asked for clarification
- Two participants ticked other even though they had not been reminded to return for an HIV/STI screen. One ticked this option because he was called back for a positive test result and one put down his reason for attendance not related to a reminder.
- The remaining participants did not have a problem with this question

Recommendation

- **Write out STI in full (Sexually Transmitted Infections) or write sexual health screen**
- **Add an option 'called by the clinic to attend for a sexual health consultation'**
- **Change the question to read 'Are you attending clinic today because you have been reminded to have a test for HIV and sexually transmitted infections?' to reflect that the reminder text message is for a 'routine' sexual health screen**

Section B: Sexual Health

Judgement

- Six (75%) of the participants read the introduction paragraph. One participant commented that this paragraph repeated some of what had been said on the first page.

Recommendation

- **Make introduction paragraph in Section B more succinct**

B1. Are you having an HIV test today?

☐ Yes   ☐ No

All participants were able to answer this question without any problems.

Recommendation

- **No need to change this question**

B2. Have you ever had an HIV test before (EXCLUDING TODAY)?

☐ YES in the last 12 months   ☐ YES 1-2 years ago

☐ YES more than 2 years ago   ☐ NO   → **If no, go to question B4**

If you have had an HIV test in the last 12 months, how many times did you have a test? ____

Objectives

Explores if the participant has ever had an HIV test before or if today is their first HIV test or how many HIV tests they have had in the past.

Cognitive: Comprehension

- One participant, whose first language is not English, misread years as weeks. He stated that he would have read this correctly if years and months were written in bold. No other participants had problems understanding the question and correctly gave an answer that indicated whether or not they had had an HIV test before today. One participant had never had an HIV test and correctly identified this

Cognitive: Recall

- One participant who correctly answered the question about how many HIV tests he had had in the past 12 months calculated the number and one estimated based on his normal routine of testing.

Logical/structural

- The participant who had never had an HIV test before correctly followed the instructions to go to question B4
- Three participants who had an HIV test in the past 12 months missed the question asking them about how many tests they had had. One

participant commented that this adjunct question was far from the original question. One participant suggested making this into two separate questions, one asking if you had had an HIV test before and the second question asking about how many tests in the last 12 months.

Recommendation

- **Place an arrow between 'YES in the last 12 months' and 'If you have had an HIV test in the last 12 months, how many times did you have a test?'**
- **Place options vertically in time order**

B3. Where did you go for your last HIV test?

☐ GP   ☐ Tested at home with a home sampling kit

☐ NHS Sexual Health/GUM clinic (**this clinic**)   ☐ Rapid test centre (e.g. THT)

☐ NHS Sexual Health/GUM clinic (**different clinic)**

☐ Private clinic   ☐ Accident & Emergency (A&E)

☐ Other, please specify _____

Objective

To understand where participants have their HIV tests and if they attend different venues/clinics

---

Cognitive: Judgement shortcuts

- Four participants did not read the answer options, but looked for the name of this clinic in the options.

Cognitive: Comprehension

- One of these participants, for whom English is not his first language, did not understand what a GUM clinic was and asked for clarification. The same participant did not know that Mortimer Market is an NHS clinic, and incorrectly assumed that it is a private clinic
- All participants understood the term sexual health clinic when probed

Recommendation

- **Change the option 'this clinic' to 'Mortimer Market Centre (this clinic)'**

- **Remove the term GUM clinic and so change the option 'NHS Sexual Health/GUM clinic (different clinic)' to 'NHS Sexual Health clinic (different clinic)'**

B4. Are you having a test for sexually transmitted infections (STI) other than HIV today (e.g. gonorrhoea, syphilis, chlamydia, hepatitis etc)?

☐ Yes   ☐ No

Cognitive: Comprehension

- One participant commented that HIV is also an STI

- None of the remaining participants had a problem answering this question

Response: Problems with answer categories

- One participant stated that he would have preferred to have had a list of STIs including HIV to pick from in response to a question that asked 'Which of the following STIs are you having a test for today?'

Recommendation

- **Since we ask about prior HIV tests and prior STI history in addition to today's test, it is wise to keep HIV and STI screen separate. An alternative is to provide an option list for tests being done today, and to then follow with questions about prior HIV tests and STI screens.**

B5. Have you ever had an STI test before (EXCLUDING TODAY)?

☐ YES in the last 12 months   ☐ YES 1-2 years ago

☐ YES more than 2 years ago   ☐ NO   **→ If no, go to question C1**

Cognitive: Comprehension

- One participant commented that HIV is also an STI
- One participant did not understand that this question excluded test carried out today.
- The same participant, for whom English is not his first language, did not understand the term STI
- None of the remaining participants had a problem answering this question

<u>Question ordering</u>

- One participant who had never had a sexual health screen before was able to follow the arrow asking him to go to question C1

Recommendations

- **Change the question to read 'Have you ever had a test for sexually transmitted infections before (EXCLUDING TODAY)?**
-

B6. In the PAST 12 MONTHS (EXCLUDING TODAY), have you been diagnosed with any of the following sexually transmitted infections?		
☐ Syphilis	☐ Hepatitis C	☐ Herpes (first episode)
☐ Gonorrhoea	☐ LGV	☐ Chlamydia
☐ Hepatitis B	☐ Other _____	

Objectives

To understand the participant's STI history

<u>Logical/structural</u>

- Three participants wanted an option for 'none of the above' or 'no'
- One participant wanted an option for 'contact of an STI'

Recommendations

- **Include an option for 'none of the above'**

SECTION C: LIFESTYLE

In this part of the questionnaire, we want to know about your sexual lifestyle. Please answer as honestly as possible. We use 'anal sex' to mean sex where one partner puts his penis into the other partner's anus, whether or not this occurs to ejaculation.

Cognitive: Comprehension

- The majority of participants read the introduction
- One participant commented that it was strange to read what anal sex means
- A comment from one participant was that the explanatory paragraph was 'boring' (CI_003)

Recommendation

- **No change**

C1. Have you EVER had anal sex with a man (either 'receptive/bottom' or 'insertive/top'), either *with or without* a condom?

☐ Yes   ☐ No   **→ If no, go to question D1**

Objectives

Part of a series of questions to explore the participant's sexual risk behaviour. This question aims to explore whether the participant has ever had anal sex. This question also guides participants to the next section if they have not had anal sex, as the sexual risk behaviour questions explore anal sex in more detail.

Cognitive: Comprehension

- One participant, for whom English is not his first language, understood this question to mean 'have you had anal sex with anyone other than your boyfriend' (CI_006)

- Several participants noted that italic emphasis was difficult to read in this part of the survey
- The remaining participants had no problems answering this question

Culturally oriented defects

- One participant commented that the wording was very formal
"Is there a way that the wording could be made a bit more friendly?" (CI_001)
- All the participants understood the terms insertive and receptive. However, many commented that they are more used to the terms top and bottom. They also commented that 'versatile' was missing from the list of types of anal sex.

"I am comfortable with top/bottom/versatile more than receptive. It is so clear." (CI_007)

Logical/structural

- All participants reported anal sex with a man, and therefore we were unable to test whether they could follow the instruction to go to question D1 if they answered 'no

Recommendation

- **Change question C1 to read 'Have you ever had anal sex with a man (either top/bottom/versatile) either WITH or WITHOUT a condom?'**

NON-STEADY MALE PARTNERS
We use the term 'non-steady partners' to mean men you have had sex with once only, and men you have sex with more than once but who you don't think of as a steady partner (including one night stands, anonymous and casual partners, regular sex buddies)

C2. IN THE PAST 3 MONTHS, how many different non-steady male partners have you had anal sex with (either 'receptive/bottom' or 'insertive/top') *with or without* **a condom?** Please estimate if you are unsure.
Number _____

Objectives

This is part of a series of questions to understand the sexual risk of participants. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.

This question aims to understand the TOTAL number of non-steady/casual partners the participant has had any anal sex with in the past 3 months.

Cognitive: Comprehension

- Five participants, including both those who have English as their first language and those took a long time to understand the explanation provided about what counts as a non-steady partner; several had to reread the explanation and one misinterpreted it to mean boyfriends.

"When I think of steady and non-steady, I think of how many people have you been with when you don't know his status…and I don't know my current partner's status" (CI_008)

- Participants suggested using the term 'casual partner' instead of non-steady partner and 'boyfriend/husband' instead of 'steady partner'

"Casual partner to me would be random guys I've met in a sauna or a club…I don't see why you can't use boyfriend. We all know what boyfriend means" (CI+001)

"Steady and non-steady partners…I feel very comfortable with casual" (CI_007)

- Of those who were able to understand the explanation quickly, one commented that the explanation provided was too long.

"Too much explanation confuses me…on top of the questions, it's too much. I am focusing on what is the question" (CI_007)

"You do explain it (non-steady partner) here, but by that point in the survey you've got several things going round in your head" (CI_001)

- One participant however found the explanation very clear and useful to calculate the number of non-steady partners.

<u>Cognitive: Recall</u>

- Four participants said that they counted the number of non-steady partners in the past three months but one acknowledged that he would estimate the number if it was a large number or if he was uncertain e.g. if he had met them in a dark room or sauna
- One participant commented that three months was a suitable time period

Recommendation

- **Change explanation to read "CASUAL MALE PARTNERS: By casual partners, we mean men you have had sex with only once, or more than once but who you wouldn't think of as a boyfriend or husband (including one-night stands and regular sex buddies)"**
- **Change question C2 to read: "In the PAST 3 MONTHS, how many different CASUAL male partners have you had anal sex with (either top/bottom/versatile) WITH or WITHOUT a condom? Please estimate if you are unsure.**
- **Move the section on casual partners to after regular partners for better flow**

C3. IN THE PAST 3 MONTHS, have you had anal sex (either 'receptive/bottom' or 'insertive/top') *without* a condom with a non-steady male partner?
☐ Yes   ☐ No   **→ If no, go to question C6**

Objectives

This is part of a series of questions to understand the sexual risk of participants. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.

This question aims to understand the TOTAL number of unprotected anal sex casual/non steady partners in the past 3 months. It also allows

for participants who have not had any UAI to miss out the questions about UAI. It allows for analysis by UAI vs no- UAI in the past 3 months.

Cognitive: Comprehension

- One participant had to refer back to the definition of non-steady and stated that he would be more comfortable with the use of casual instead of non-steady

"By saying non-steady, I have to think back to your definition. If you say casual, I understand that" (CI_002)

- One participant initially did not notice that this question was asking about unprotected anal sex, and felt that more emphasis was needed on the word 'without (a condom)'
- The remaining participants did not have a problem answering this question.

Question ordering issues

- The two respondents who report no unprotected anal sex had no problems following the instructions to go to question C6.

Recommendation

- **Change question to read "In the PAST 3 MONTHS, have you had anal sex (either top/bottom/versatile) WITHOUT a condom with a CASUAL male partner?**

C4. IN THE PAST 3 MONTHS, when you had anal sex with non-steady male partners *without* a condom,were you…? (please tick only one)

☐ Always insertive/top   ☐ Mostly insertive/top

☐ Always receptive/bottom   ☐ Mostly receptive/bottom

☐ Versatile- equally insertive/top and receptive/bottom

Objectives

253

This is part of a series of questions to understand the sexual risk of participants. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.

This question aims to understand the type of UAI that participants had in the past 3 months with casual/non steady partners. It does not ask about sero-positioning, although the participant may practice it.

Cognitive: Comprehension

- One participant incorrectly answered for his boyfriend instead of non-steady male partners
- The remaining participants had no problems answering this question

Cognitive: Recall

- One participant noted that he would think back to all the partners that he had had sex with, but also that he may use his default preference to answer the question

Recommendation

- **Change the question to read "In the PAST 3 MONTHS, when you had anal sex with CASUAL male partners WITHOUT a condom, were you…? (please tick only one)**

C5. IN THE PAST 3 MONTHS, with how many different non-steady male partners were you the receptive/bottom sex partner *without* a condom? Please estimate if you are unsure.

Number _____

Of these, how many did you:

Know to be HIV positive   _____

Know to be HIV negative   _____

Did not know their HIV status _____

Objectives

> **This is part of a series of questions to understand the sexual risk of participants. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.**
>
> **This question aims to understand receptive UAI practice and HIV exposure/risk with casual/non steady partners. It does not ask about serosorting, although the participant may practice it.**

Cognitive: Comprehension

- One respondent wrongly assumed that this question was referring to insertive/receptive with/without a condom.
- One respondent assumed the question was asking 'Did you know their status' and answered 'yes' rather than giving a number
- The remainder of participants found this question easy to answer

Judgement

- One respondent noted that he would not be able to think about the status of all his casual partners, and would probably just tick 'did not know status'

Response answer categories

- All respondents were happier having a blank number field to complete than having number ranges

Logical/structural

- Respondents who answered 'zero' to the first part of this question correctly left the rest of the question blank. However, an arrow to question C6 might be useful

Recommendation

- **Rephrase the question 'In the PAST 3 MONTHS, with how many different CASUAL male partners were you the BOTTOM sex partner WITHOUT a condom? Please estimate if you are unsure**
- **Add an arrow next to number that states 'if zero →C6"**

STEADY MALE PARTNER
We use the term 'steady partner' to refer to boyfriends or husbands that mean you are not 'single', but not to partners who are simply sex buddies.

Cognitive: Comprehension

- One respondent skim read this explanation and summarised it as "so that's the opposite of before" (CI_003)
- One respondent took steady male partner to include casual partners who may become a boyfriend in the future, and so included this partner in both non-steady and steady categories
- Most respondents commented that they were more familiar with the terms boyfriend or husband than steady male partner

Recommendations

- **Consider changing the title to read 'REGULAR MALE PARTNER': By REGULAR male partner, we mean boyfriend/husband to mean that you are not single, but do not include partners who are simply sex buddies.**

C6. Do you currently have a steady male partner?

☐ Yes   → For how long? _____years _____months

☐ No   → **If no, go to question C12**

Objectives

This is part of a series of questions to understand the sexual risk of participants within a steady male partnership. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.

This question aims to elucidate whether the participant has a steady male partner and the length of this relationship. It also allows for participants who do not currently have a steady male partner to skip the following question series.

<u>Cognitive: Comprehension</u>

- One participant had to refer back to the explanation of steady male partners to be able to answer the question

<u>Cognitive: Recall</u>

- All participants who had a steady male partner were able to calculate the length of time they had been in a relationship with them

<u>Logical/structural</u>

- One participant who answered 'no' to this question missed the prompt to go to QC12
- Several participants noticed that there was no question C12

Recommendation

- **Change prompt for 'no' to 'if no, go to question C6'**
- **Change question to read 'Do you currently have a REGULAR male partner?**

C7. Do you know your current steady male partner's HIV status?

☐ YES, HIV negative   ☐ YES, HIV positive   ☐ I don't know his status

Objectives

This is part of a series of questions to understand the sexual risk of participants within a steady male partnership. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.

This question aims to determine whether the participant is in a sero-discordant partnership.

<u>Cognitive: Comprehension</u>

- One respondent commented that this question could be confusing for those who have more than one concurrent steady partner
- This question was only applicable to four respondents all of whom had no problems answering this question

Recommendation

- **Change this question to read 'Do you know your REGULAR male partner's HIV status?**

C8. IN THE PAST 3 MONTHS, how many different steady male partners have you had anal sex with (either 'receptive/bottom' or 'insertive/top') *with or without* a condom? Please estimate if you are unsure.

Number _____

Objectives

This is part of a series of questions to understand the sexual risk of participants. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.

This question aims to understand the TOTAL number of steady partners the participant has had any anal sex with in the past 3 months.

Cognitive: Comprehension

- Of the four participants for whom this question was applicable, two found it confusing. One answered for non-steady male partners. One commented that we did not take into account multiple steady partners earlier in the questions (C6), but try to take account for it in C8, which he found confusing

Recommendation

- **Remove this question. The objective of these series of questions is to understand whether the participant is in a serodiscordant steady partnership and if so, is anal sex protected or not. This question does not add value.**

C9. IN THE PAST 3 MONTHS , have you had anal sex (either 'receptive/bottom' or 'insertive/top') *without* **a condom with a steady male partner?** Please estimate if you are unsure.

☐ Yes ☐ No

Objectives

This is part of a series of questions to understand the sexual risk of participants. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.

This question aims to understand whether the participant has had UAI with a steady male partner in the past 3 months.

Cognitive: Comprehension

- Two of the four participants answering this question had to reread the question before answering and had to refer back to the definition of steady male partner to be able to answer

Logical/structural

- One participant missed the arrow next to the answer 'no' and incorrectly answered C10 subsequently
- The prompt asks participants to go to question C12, which does not exist

Recommendation

- **Change the question to read 'In the PAST 3 MONTHS, have you had anal sex (top/bottom/versatile) WITHOUT a condom with your REGULAR male partner?**
- **Move the arrow closer to the answer 'no' and change the prompt to read, 'If no, go to question C6'**

C10. IN THE PAST 3 MONTHS, when you had anal sex with a steady male partner *without* **a condom, were you...?** (please tick only one)

☐ Always insertive/top ☐ Mostly insertive/top

☐ Always receptive/bottom ☐ Mostly receptive/bottom

☐ Versatile- equally insertive/top and receptive/bottom

Objectives

This is part of a series of questions to understand the sexual risk of participants. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.

This question aims to understand the type of UAI that participants had in the past 3 months with steady male partners. It does not ask about sero-positioning, although the participant may practice it.

Cognitive: Comprehension

- Three participants answered this question and did not have problems

Recommendation

- **Change question to read 'In the PAST 3 MONTHS, when you had anal sex with a REGULAR male partner WITHOUT a condom, were you…? Please tick only one.**

C11. IN THE PAST 3 MONTHS, with how many different steady male partners were you the receptive/bottom sex partner *without* a condom? Please estimate if you are unsure.

Number _____

Of these, how many did you:

Know to be HIV positive _____

Know to be HIV negative _____

Did not know their HIV status _____

Objectives

This is part of a series of questions to understand the sexual risk of participants. The questions aim to ask about sexual risk in a step-wise manner to allow all partners to be accounted for.

> **This question aims to understand receptive UAI practice and HIV exposure/risk with steady male partners. It does not ask about serosorting, although the participant may practice it.**

Cognitive: Comprehension

- One participant noted that this question duplicates C7 if the respondent only has one steady male partner
- One participant had to read the question twice before he understood it and one participant incorrectly answered about partners he had protected and unprotected anal sex with

Recommendation

- **Remove this question. Question C7 in association with C9 already provides the information required about unprotected anal sex and HIV status of the partner. C10 will give an idea about whether sex is mainly receptive/insertive/versatile with the steady male partner.**

Section D: Your views on being reminded to return for a HIV test and sexual health screen

SECTION D: YOUR VIEWS ON BEING REMINDED TO RETURN FOR A HIV TEST AND SEXUAL HEALTH SCREEN

We want to understand your views on how often you want to be tested for HIV and sexually transmitted diseases, where you would like to be tested, how you would like to be reminded and what would encourage you or dissuade you from testing if we sent you a reminder.

Cognition: Comprehension

- Few participants read this introduction paragraph

Recommendation

- **Remove introductory paragraph**

HIV AND STI TESTING FREQUENCY

D1. In the UK, it is recommended that gay and bisexual men should be tested for HIV every 12 months. Do you agree with this recommendation?

☐ Strongly   ☐ Tend to   ☐ Undecided   ☐ Tend to   ☐ Strongly
   agree   agree   or no opinion   disagree   disagree

If you tend to disagree/strongly disagree, why is this? _____

Objectives

This is part of a series of questions to explore participants' views on active recall for HIV/STI testing.

This question aims to explore whether participants agree with the policy of annual HIV testing.

Cognitive: Comprehension

- All participants were able to understand this question
- Those that disagreed were able to provide an answer for why in the correct place, except one who left it blank

"I think every 12 months is too long. If they've had unprotected sex and caught it (HIV), that's 11 months without knowing" (CI_002)

"It should be a routine" (CI_007)

Logical: structural

- All participants who disagreed were able to follow the instructions to explain why. However, one participant almost missed this part of the question

Response/answer categories

- Two participants commented that they like the Likert scale
- One participant commented that spaces for 'other' or where explanations were required were too short in general

Recommendation

- **Place an arrow from tend to disagree/strongly disagree options to the next part of the question 'If you tend to disagree/strongly disagree….'**
- **Increase space for answer to supplementary question**

D2. Do you test for HIV and STIs as often as you would like to?

☐ Yes   ☐ No

Objectives

Aims to understand whether participants test for HIV and STIs as often as they would like based on their sexual risk as opposed to what they feel should be national guidance.

Cognitive: Comprehension

- Some participants had to read the question twice to understand that this question was different to D1 and was asking about personal testing frequency based on personal risk behaviours. However, after re-reading the question, all participants understood the difference.

Recommendation

- **Change question to read 'Do YOU test for HIV and sexually transmitted infections as often as you would like to?**

D3. How often would *you* want to be tested for HIV and STIs?

☐ Every month   ☐ Every 3 months   ☐ Every 6 months

☐ Every 12 months   ☐ After every new partner   ☐ Other, please specify _____

Objectives

This is part of a series of questions to explore participants' views on active recall for HIV/STI testing.

This question explores how often the participant thinks they want to be tested for HIV/STIs

---

Cognitive: Comprehension

- Two participants had to read the question twice to understand that this question was different to D1 and was asking about personal testing frequency based on personal risk behaviours. However, after re-reading the question, all participants understood the difference.

Response: Problems with answer categories

- Three participants comments that they wanted more answer options or the option to elaborate, since their response was more complex than picking one time option

"This depends on a lot of factors. If you're in a relationship it would be less often. After every new partner is also the wrong thing, as there's an element of distrust. I'm going to say every 6 months because I'm in a relationship. If I wasn't it depends on how many partners. If I was in a relationship I'd say every 6 months and after every new partner if I was sleeping around" (CI_008)

"I would say after every new partner and every 6 months"

- One participant comments that the space for 'other' was too short
- Several participants commented that the question does not specify whether you can pick more than one option or not.

Recommendation:

- **Change question to read 'How often would YOU want to be tested for HIV and sexually transmitted infections AT THE MOMENT? You may tick more than one answer' This should capture how often the participant wanted to be tested based on his current relationship/sexual lifestyle. This question may need to be retested for cognition.**

D4. Here are some statements about regular HIV and STI testing. Please read each statement carefully and place a tick in the box that is closest to your viewpoint. Give only one answer for each row.	Strongly agree	Tend to agree	Undecided or no opinion	Tend to disagree	Strongly disagree
a) I don't believe that I am at risk of HIV	☐	☐	☐	☐	☐
b) Fear of a positive test result puts me off testing	☐	☐	☐	☐	☐
c) I don't want to put others at risk	☐	☐	☐	☐	☐
d) Most of my gay friends have had an HIV test	☐	☐	☐	☐	☐

Objectives

This is part of a series of questions to explore participants' views on active recall for HIV/STI testing.

This question explores participants' beliefs about HIV testing in general. In particular:

Statement A: explores risk perception

Statement B: explores barriers to HIV testing

Statement C: explores drivers to HIV testing

Statement D: explores social norms around HIV testing

Issues with objective: Unclear objective question

- One participant commented that he was not clear that this set of questions matched the objective of the survey tool to assess attitudes to active recall for HIV/STI testing

"I would not know what you are trying to achieve with (these questions)" (CI_003)

Cognitive: Comprehension

- All participants took a long time to answer these multi-option questions
- The majority of participants struggled to understand negative statements and match them to an opinion. They all commented that it would be easier to have a list of positive statements, making it easier to match them to the response options.
- One participant, for whom English is not his first language, misunderstood D4c as stating that 'he was a risk to others for HIV'. Another participant had to ask for clarification for this question

"So that means that I am at some risk?" CI_005

- One participant did not understand initially that he had to give a personal opinion rather than applying risk guidelines to his sexual lifestyle
- One participant found D4d difficult to answer as he does not have gay friends

Recommendation

- **Keep this set of questions, but change negative statements to positive ones. E.g. Change D4a to read 'I believe that I am at risk of becoming infected with HIV'. This is the only set of questions about risk perception and will influence testing behaviours.**

HIV AND STI TESTING VENUES

D5. Where would you want to go for a regular HIV and STI test?

☐ GP

☐ NHS Sexual Health/GUM clinic

☐ Private sexual health clinic

☐ Other, please specify _____

☐ Test at home with a home sampling kit

☐ Rapid test centre (e.g. THT)

☐ Accident & Emergency (A&E)

> *Objectives*
>
> **This is part of a series of questions to explore participants' views on active recall for HIV/STI testing.**
>
> **This question explores preferences for HIV/STI testing venue in general**

<u>Cognition: Comprehension</u>

- All participants understood the question and read through all the response options before answering

"GU clinic, because private costs money, GP isn't the first place you want to go to…GU clinics advertise things about being gay…GP clinics aren't as visually welcoming" (CI_001)

"I prefer the GUM clinic, but the queues are getting too long" (CI_002)

<u>Response: Problems with answer categories</u>

- The majority of participants commented that there was no guidance on whether they could pick more than one option
- One participant for whom English is not his first language, did not know what NHS meant
- Several participants commented that they did not know what THT stood for
- One participant did not know what GUM stood for
- None of the participants had a frame of reference for or experience with home sampling

"Test at home, as it is new, I don't have experience with that" (CI_007)

Recommendation

- **Change question to read "Where would you want to go for a regular test for HIV and sexually transmitted infections? (you can tick more than one)"**

- **Change answer option "NHS Sexual Health/GUM clinic" to "NHS Sexual Health clinic"**
- **Change answer option "Rapid test centre (e.g. THT)" to "Rapid test centre (e.g. Terrence Higgins Trust)**
- **Move this section (HIV and STI testing venues) to after the section on testing reminders**
- **Provide a short explanation for home sampling**

D6. Which of the following factors are important to you when deciding where to have a regular HIV and STI test? (you can tick more than one)

☐ Proximity of the clinic to place of work/home   ☐ After hours service

☐ Confidentiality of the service   ☐ Weekend opening

☐ A personal recommendation   ☐ Same day results

☐ Option to home sample   ☐ Previous use of clinic

☐ Other, please specify _____

Objectives

This is part of a series of questions to explore participants' views on active recall for HIV/STI testing.

This question explores drivers and barriers to regular HIV testing in general at individual and clinic level.

Cognitive: Comprehension

- All participants understood the question and were quick to answer. They verbalised the reasons why they would pick the answer that they did

"The option to home sample…the factor is that you can do it at your leisure" (CI_008)

"Weekend opening…the major factor would be what I'd done on a Saturday night" (CI_008)

"Same day results wouldn't be too bad. I'd compare it to another clinic, and if they're going to say they'd do it the same day, then I probably would (go there)" (CI_008)

"I'm going to tend to like the place that can help me as soon as possible" (CI_007)

<u>Response: Problem with answer categories</u>

- All participants read through the answer categories before answering the question
- Several participants commented that they assume that the service in the NHS and in particular in a GUM clinic is confidential, so it is not a factor in deciding where to go
- One participant did not notice that he could tick more than one response option
- One participant commented that he would like to see shorter waiting times. He did not write this under 'other', but noted that he would have picked this if it was an option

Recommendation

- **Change the question to read "Which of the following factors are important to you when deciding where to have a regular test for HIV and sexually transmitted infections? (you can tick more than one)**
- **Keep 'Confidentiality of the service" in response options, as this has been identified in systematic reviews to be an important factor for patients(78).**
- **Add 'short waiting times' as an option**

D7. Here are some statements about testing for HIV and STIs at home with a home sampling kit. Please read each statement carefully and place a tick in the box that is closest to your viewpoint. Give only one answer for each row.					
	Strongly agree	Tend to agree	Undecided or no opinion	Tend to disagree	Strongly disagree

a) Testing for HIV and STIs with a home sampling kit is convenient for me	☐	☐	☐	☐	☐
b) Receiving a home sampling kit for HIV and STIs at my home is not confidential	☐	☐	☐	☐	☐
c) Testing for HIV and STIs with a home sampling kit is accurate	☐	☐	☐	☐	☐
d) I would be willing to pay a small fee to use a home sampling kit to test for HIV and STIs	☐	☐	☐	☐	☐
e) I prefer seeing a clinician for my **HIV** test over using a home sampling kit	☐	☐	☐	☐	☐
f) I prefer seeing a clinician for my **STI** test over using a home sampling kit	☐	☐	☐	☐	☐

Issues with objective

- Several participants commented that D7b was difficult to interpret as receiving a kit in the post is not necessarily confidential. However, they wondered whether we wanted to ask whether receiving a home sampling kit in the post is a problem for the patient?

"the more pertinent question is does it bother me…it's not confidential in that I share (a house) with other people" (CI_007)

"The question is, can anyone else receive it apart from me" (CI_003)- left answer blank

- One participant felt that D7e and f (I would prefer seeing a clinician for my HIV/STI test over using a home sampling kit) was a repetition of D5 (Where would you want to go for a regular HIV and STI test)
- The same participant also commented that it would be better to ask about preference regarding home sampling compared to clinician before asking about willingness to pay a fee, as those who do not want to use home sampling are unlikely to want to pay a fee for it.

"I would have to ask e before d and then d becomes irrelevant" (CI_003)

Cognitive: Comprehension

- All participants took a very long time to answer this series of questions, in part as they did not have a frame of reference for home sampling, but also as they found some of the questions difficult to understand and had to reread them multiple times.
- One participant commented that D7a did not make sense to him, as he understood home sampling to be convenient by definition as the kit is posted to the patient. He therefore ticked 'strongly agree', but this was based on a definition, not an opinion.

"Is that the right question? By definition it's convenient. For me it's a non-question" (CI_003)

- The majority of participants had difficulty correctly understanding a negative statement (D7b) after a positive one (D7a) and some incorrectly thought that D7b stated that 'receiving a home sampling kit for HIV and STIs at my home is confidential'
- All participants commented that they did not know about the accuracy of home sampling and therefore found it difficult to comment, with some leaving that question blank

"I can't answer that as I don't know" (CI_002)

"I don't know. You would hope so, so I don't know whether that question works" (CI_003)

- One participant did not realise that D7e was asking about HIV and D7f was asking about STIs and thought that the questions had been repeated.

Cognitive: Judgement

- None of the participants had used home sampling before. None had correctly heard of it before- one mistakenly thought he could buy it over

the counter at Boots the Chemist. Therefore participants did not have a frame of reference from which to answer the question.

"I don't have experience for the moment" (CI_007)

<u>Response: problem with answer categories</u>

- Several participants commented that they wanted an option for 'not applicable' or 'not an issue for me'

"It's not that I don't have an opinion on it, but there is no opinion that fits my needs" (CI_003)

- In response to D7d (I would be willing to pay a small fee to use a home sampling kit to test for HIV and STIs), two participants commented that they would be willing to pay a fee, but would not necessarily use the kit

"I would tick strongly agree, but I wouldn't do it" (CI_003)

"I would pay for it on the basis that I could keep it in the cupboard" (CI_008)

One participant answered strongly agree even though he would not want to use a home sampling kit. He explained that this was because he understood the question to imply that you were going to receive a home sampling kit regardless of your opinion on the kits.

"What I understood is..I disagree because I'm not willing to take it home, I prefer to come to clinic to take it. Once I agree to receive a kit at home, am I willing to pay? Yes. But in my case, I prefer to come to clinic" (CI_006)

Recommendation

- **Remove this series of questions. Home sampling is a form of active recall for HIV/STI testing. It is therefore important to explore some of the drivers and barriers to home sampling. However, many participants had difficulty understanding this series of questions, misunderstood some questions and took a long time to complete the section.**
- **The question that is important were:**

- o **Would you prefer to see a clinician or receive a home sampling kit to test for HIV and sexually transmitted infections?**
- **It is confusing for participants to separate HIV and STIs, and since only a home sampling kit for HIV is currently available, it is easier to ask about HIV home sampling only**
- **Although it would be interesting to understand whether participants believed that a home sampling kit is convenient for them and confidential, participants found these statements confusing. These dimensions could be explored in more detail in in-depth interviews.**

HIV AND STI TESTING REMINDERS

D8. If you were to receive a reminder to be tested for HIV and STIs regularly, which type of reminder would you prefer?

☐ Text message   ☐ Phone call

☐ Letter   ☐ Email

☐ Test sent to my home   ☐ I do not want a reminder

☐ Other, please specify _____

Objectives

This is part of a series of questions to explore participants' views on active recall for HIV/STI testing.

This question explores the type of reminder participants would prefer to receive for HIV/STI testing

---

Problems with answer categories

- Four participants commented that they did not know whether they could pick more than one answer for this question

Cognitive: Comprehension

274

- None of the participants had problems answering this question

Recommendation

- **Change question to read "If you were to receive a reminder to be tested for HIV and sexually transmitted infections regularly, which type of reminder would you prefer? (you can tick more than one)**

D9. Here are some statements about HIV and STI testing reminders. Please read each statement carefully and place a tick in the box that is closest to your viewpoint. Give only one answer for each row.	Strongly agree	Tend to agree	Undecided or no opinion	Tend to disagree	Strongly disagree
a) I like being reminded to check my health status	☐	☐	☐	☐	☐
b) I am confident that I would be able to return for a repeat HIV and STI test in 3 months time if I was reminded to do so	☐	☐	☐	☐	☐
c) I am concerned that a reminder to have a HIV and STI test would breach my confidentiality	☐	☐	☐	☐	☐
h) I am concerned that receiving a reminder to have a HIV and STI test would stigmatise me	☐	☐	☐	☐	☐

Objectives

This is part of a series of questions to explore participants' views on active recall for HIV/STI testing.

This question explores participants beliefs about home testing for HIV. In particular:

Statement A: explores drivers to active recall

Statement B: explores intention

Statement C: explores barriers to active recall

Statement D: explores barriers to home sampling

<u>Question/objective mismatch</u>

- One participant commented that he did not like the use of the phrase 'repeat HIV and STI test' as he associated the word 'repeat' with the initial test instead of a routine screen, as intended in the objectives

<u>Cognition: Comprehension</u>

- The majority of participants were able to answer this series of questions without a problem
- However, one participant, for whom English is not his first language, did not appear to understand D9c and D9h
- "I try to say something positive…I think I got it wrong" (CI_006)

<u>Cognition: Judgement</u>

- Several participants answered this question for the mode of reminder they had picked in the previous question D8.
- One participant commented that the response to D9c (I am concerned that a reminder to have a HIV and STI test would breach my confidentiality) depended on which form of reminder you were referring to when answering this question

"Depends on what format (the reminder) is. If someone opens a letter, it's not confidential" (CI_001)

- One participant took some time to answer D9b as he felt that it was a complex decision about whether or not to return in three months time depending on current sexual risk

<u>Question ordering</u>

- One participant noted that the ordering of questions was incorrect
- One participant noted that D9b was a duplication of D11

Recommendation

- **Change question to read 'Here are some statements about reminders for testing for HIV and sexually transmitted infections.**

Please read each statement carefully and place a tick in the box closest to your viewpoint. Give only one answer for each row.

- **Remove D9b as it is asked in D11**

- **Change D9c to read 'I am concerned that a reminder to have a test for HIV and sexually transmitted infections would breach my confidentiality' and change this numbering to D9b**

- **Change D9h to read ' I am concerned that receiving a reminder to have a test for HIV and sexually transmitted infections would stigmatise me' and change the numbering to D9c.**

- **Although D9a is a positive statement and the following two questions will be negative statements, they are easier to read without a negative word in the sentence**

D11. If you were sent a reminder to return for a HIV and STI test in 3 months time, how likely are you to return to have the test?

☐ Extremely likely ☐ Quite likely ☐ Not very likely ☐ Extremely unlikely

---

Objectives

This is part of a series of questions to explore participants' views on active recall for HIV/STI testing.

This question explores participants intentions to return if actively recalled for an HIV/STI screen

---

Question/objective mismatch

- One participant commented that he did not like the use of the phrase 'repeat HIV and STI test' as he associated the word 'repeat' with the initial test instead of a routine screen, as intended in the objectives

"To return, the first thing for me, return is associated with the last one (last test), that there is something wrong. (I prefer) To come for a new screen or your periodical screen or regular screen, it's time for your check-up. But to

return or to repeat, straight away for me, it's like it scares me, why do I have to repeat?" (CI_007)

- Several participants commented that this question repeated the question asked in D9b

- One participant commented that this question should be earlier in the survey, as it is the question that most closely matches the overall objective of the survey. If participants have given up by this point, there will be lower completion rates for this question.

Cognitive: Comprehension

- The majority of participants did not have a problem answering this question

Cognitive: Judgement

- Two participants commented that their response to this question depends on their relationship status at the time.

"It depends. At the moment, no. I'm probably not going to come back after 3 months, but probably at 6 months. I would tick quite likely" (CI_006)

Cognitive: Problem with answer categories

- One respondent suggested that it would be easier to answer the question if there were time category options, e.g. Would you have a test for HIV and sexually transmitted infections if you were sent a reminder to have these tests at 3/6/12 months?

"You would tick the month that you would actually be happy to attend" (CI_006)

Logical/structural

- One participant noticed that D10 was missing in the ordering of question numbers

Recommendation

- **Change question to include two questions:**
  - **The first question tests intention and should include a Likert scale to appropriately test behavioural intervention: "If you were sent a reminder to have a test for HIV and sexually transmitted infections, how likely are you to have the test?"**
  - **The second question explore how often the participant wants the reminder: "How often would you want to receive a reminder to have a test for HIV and sexually transmitted infections?"**
- **Move the section on HIV and STI testing reminders to before HIV and STI testing venues**
- **Change question number to D10**

D12. Which of the following would make you more likely to test for HIV and STIs in 3 months time?

☐ Receiving a reminder to test   ☐ Unprotected anal sex within the past 3 months

☐ Receiving a STI and HIV home sampling kit at my clinic visit for future use

☐ Receiving a STI and HIV home sampling kit in the post

☐ Other, please specify _____

Objectives

This is part of a series of questions to explore participants' views on active recall for HIV/STI testing.

This question explores drivers to active recall for HIV/STI screening.

Cognitive: Comprehension

- The majority of participants did not have a problem answering this question

- One participants took a long time answering this question, as he felt that he would be unlikely to have a test in three months time, but felt picked the option that fitted best with his current sexual lifestyle.

"Definitely receiving a STI and HIV home sampling kit in the post, definitely easiest. Just do it and I don't have to go anywhere…If you send me a kit and I've been ok, I can skip this one and wait for the next one" (CI_007)

<u>Cognitive: problem with answer categories</u>

- Six participants wanted to know if they could tick more than one answer category
- One respondent wanted the answer category 'unprotected anal sex within the past three months' to clarify whether this included boyfriends or not

"If I was with my boyfriend and got a reminder, I would probably ignore it and wait another three months" (CI_008)

Recommendation

- **Change question to read "Which of the following would make you more likely to test for HIV and sexually transmitted infections in 3 months time (you can tick more than one)**
- **Change question number to D11**
- **Change answer category "unprotected anal sex within the past 3 months" to "unprotected anal sex with a CASUAL partner in the past 3 months**

SECTION E: DEMOGRAPHICS

E1. Which ethnic group best describes you? (Please tick ONE ONLY)

☐ White   ☐ Black (Africa/Caribbean/Other)

☐ South East Asian   ☐ Asian (Indian/Pakistani/Bengali)

☐ Mixed/ Other, please specify _____

Objectives

This question aims to determine the participant's ethnicity to allow for analysis by this demographic.

<u>Cognitive: Comprehension</u>

- All participants were able to fill this question out without a problem

<u>Cognitive: problem with answer categories</u>

- Two participants wanted a longer list of categories, consistent with the clinic registration form
- One participant commented that he liked the short list of options, as he finds the longer lists racially insensitive

Recommendation

- **No change to this question**

E2. Were you born in the UK?

☐ Yes   ☐ No

If NO, which country were you born in? _____

When did you first move to the UK?
☐ Less than 1 year ago   ☐ 1 to 5 years ago   ☐ More than 5 years ago

---

Objectives

> **This question aims to differentiate between UK born, new migrant and longer-term migrant participants to allow for analysis using this demographic.**

Cognitive: Comprehension

- The majority of participants had no problems answering this question

Cognitive: Recall

- All non-UK born participants were able to accurately calculate in years and months when they first moved to the UK

Logical/structural

- Two participants incorrectly tried to answer the second part of the question even though they were UK born

Recommendation

- **Place a prompt next to answer option 'yes' to go to question E3**
- **Place an arrow next to answer 'no' to guide the participant to the supplementary questions**

E3. Which of the following best describes your current occupation?

☐ Employed full-time   ☐ Employed part-time
☐ Self-employed   ☐ Unemployed
☐ Student   ☐ Retired
☐ Long-term sick leave/medically retired   ☐ Other, please specify _____

> *Objectives*
>
> **This question aims to determine whether the participant is in full-time or part-time employment or unemployed (or other) to allow fro analysis using this demographic.**

Cognitive: Comprehension

- All participants were able to answer this question without a problem

Cognitive: problems with answer categories

- One participant was a student and employed part-time, and wanted to know if he could tick more than one response option

Recommendation

- **Change question to read 'Which of the following best describes your MAIN current occupation (please tick only one)"**
- **Make the answer space for 'other' longer**

E4. At what level did you COMPLETE your education?

☐ Still in full-time or part-time education   ☐ A levels (or equivalent at age 18
☐ Finished education with no qualifications   ☐ University degree or above
☐ O levels/ GCSEs (or equivalent at age 16))   ☐ Other qualifications, please specify _____

Objectives

This question aims to determine the participants' levels of education to allow for analysis by this demographic.

Cognitive: Comprehension

- All participants had no problems answering this question

Cognitive: Problems with answer categories

- One participant commented that the majority of participants would have completed a higher degree, and he would find it easier to answer this question if higher degrees were higher up in the list
- One participant commented that the response options were UK-centric. Foreign born respondents may not understand what GCSEs and A-levels are.
- One respondent tried to answer that he had a Diploma and struggled to find an appropriate answer category. He ticked 'other'

Recommendation

- **Make the answer space for 'other' longer**

- **The majority of interviews were carried out in evening clinics, where participants are more likely to have a higher degree and attend after working hours. However, this is not necessarily the case during daytime clinics. Therefore, I recommend using the validated standardised question in the original survey tool.**

E5. Which of the following options best describes how you think of yourself?

☐ Heterosexual/straight ☐ Gay/lesbian
☐ Bisexual ☐ Other, please specify_____

Objectives

This question aims to determine the participants' reported sexual orientation to allow for analysis by this demographic.

Cognitive: Comprehension

- None of the participants had a problem answering this question

Cognitive: problems with answer categories

- One participant commented that lesbian did not apply to the survey as it was for men

Recommendation

- **Change answer category 'gay/lesbian' to 'gay or man who has sex with men'**

We would like to have a longer discussion to explore some of the issues around HIV and STI testing reminders. Would you be willing to participate in a one hour interview?

We will only be contacting a small number of participants. By answering 'yes' to this question, you agree to us accessing your contact details from the Mortimer Market clinic database to invite you for interview.

☐ Yes ☐ No

Objectives

> **This question aims to provide the researcher with a list of potential participants for the in-depth interviews.**

Cognitive: comprehension

- Two participants asked whether the in-depth interviews what they had just taken part in

Issues with objective: Unclear objective question

- One participant commented that as this was a long survey that asked detailed questions about a lot of different topics, the response rate to the final question may be low due to survey exhaustion
- Another participant ticked 'yes', but seemed surprised by the question

Recommendation

- **No change to this question**

<u>**Final page**</u>

- Only one respondent read the whole of the final page

4. Questionnaire survey

4.1 Ethics approval letter for survey and in-depth interviews

05 December 2013

Dear Dr Desai

Study title: **Facilitators and barriers to active recall for HIV and STI testing of MSM at high risk of HIV infection in Genitourinary Medicine clinics**
REC reference: **13/YH/0347**
IRAS project ID: **129591**

Thank you for your letter of 3rd December. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 19 November 2013

Documents received

The documents received were as follows:

Document	Version	Date
Covering Letter		26 November 2013
Participant Consent Form: Cognitive Interview	0.2	19 November 2013
Participant Consent Form: IDI	0.2	19 November 2013
Participant Information Sheet: Cognitive Interview	0.5	19 November 2013
Participant Information Sheet: IDI	0.5	19 November 2013

Approved documents

The final list of approved documentation for the   study is therefore as follows:

Document	Version	Date

Covering Letter	Letter from Dr Monica Desai	07 October 2013
Covering Letter		26 November 2013
Interview Schedules/Topic Guides	Guide for Cognitive Interviews / Version 0.2	20 September 2013
Interview Schedules/Topic Guides	Guide for One to One Interviews	20 September 2013
Investigator CV	CV for Dr Monica Desai	05 September 2013
Other: Letter from Funder (BHIVA)		19 July 2013
Participant Consent Form: Cognitive Interview	0.2	19 November 2013
Participant Consent Form: IDI	0.2	19 November 2013
Participant Information Sheet: Cognitive Interview	0.5	19 November 2013
Participant Information Sheet: IDI	0.5	19 November 2013
Protocol	Version FINAL	05 September 2013
Questionnaire: Non Validated Questionnaire	Final Version	05 September 2013
REC application	Version 3.5	07 October 2013

You should ensure that the sponsor has a copy of the final documentation for the study.   It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/YH/0347   **Please quote this number on all correspondence**

Yours sincerely

E-mail: nrescommittee.yorkandhumber-leedswest@nhs.net

Copy to:

1.2 Sample size calculation

Estimate of the precision around the willingness to be actively recalled for a repeat HIV/STI screen

Hypothesis: 50% of those surveyed will be willing to reattend

Therefore the following assumptions are made:

Proportion (P)- 50%

Precision (A)= consider different options: 1%, 5%, 10%, 15%

95% confidence interval (Z)

Sample size = $(P[1-P])/((A^2/Z^2))$

Precision (A)	Sample size (SS)
0.01	9604
0.05	384
0.1	96
0.15	43

Assuming response rates of 30%, 40%, 50%, the sample sizes required are:

Precision		0.01	0.05	0.1	0.15
Response rate					
	0.3	32013	1281	320	142
	0.4	24010	960	240	107
	0.5	19208	768	192	85

A response rate of 30% with 10% precision requires a sample size of 320.

Odds of willingness to attend among those reporting UAI compared to no UAI

Assumptions:

1. 2/3 of the sample report no UAI, 1/3 of the sample report UAI (i.e. ratio of cases to controls is 1:2

2. 50% willingness to reattend among non-UAI patients

3. Power 80%, 90%

4. Alpha 0.05

Hypothesis: Significantly more patients that report UAI state that they are willing/very willing to reattend compared to patients that do not report UAI

Null hypothesis: There is no difference in willingness to reattend between UAI and no UAI patients

Sample sizes required:

Odds of MSM reporting UAI stating that they are willing/very willing to test or retest compared to MSM who report no UAI	power 0.8	Power 0.9	Proportion of non-UAI MSM willing/very willing to test or retest	Proportion of UAI MSM willing/very willing to test or retest
2	323	420	0.5	0.67
3	150	192	0.5	0.75
4	104	131	0.5	0.80
5	86	107	0.5	0.83
	alpha 0.05	alpha 0.05		

Assuming a 30% response rate, the sample size required is:

Odds of MSM reporting UAI stating that they are willing/very willing to test or retest compared to MSM who report no UAI	power 0.8	Power 0.9	Proportion of non-UAI MSM willing/very willing to test or retest	Proportion of UAI MSM willing/very willing to test or retest
2	1067	1400	0.35	0.52
3	500	640	0.35	0.62
4	347	437	0.35	0.68
5	287	357	0.35	0.73
	alpha 0.05	alpha 0.05		

An odds ratio of three for MSM reporting UAI stating that they are willing/very willing to retest compared to MSM reporting no UAI is feasible. The hypothesised sample size is 1067. This allows both the odds and precision estimates to be fulfilled.

Recall Study

A survey about your views on being reminded to have a HIV/sexual health screen

SMS

@

Clinic ID:

Date of clinic visit: ___ / ___ / ___

Date of birth: ___ / ___ / ___

Public Health England

Central and North West London NHS
NHS Foundation Trust

UCL

- This is a survey for gay or other men who have sex with men

- We want to understand your views on how often you want to be tested for HIV and sexually transmitted infections, where you would like to be tested, how you would like to be reminded and what would encourage or dissuade you from testing if we sent you a reminder.

- Please answer all the questions as fully as you can. You are free to leave any question you do not want to answer.

- Please do NOT write your name on this survey. Your answers will NOT be seen by the doctors and nurses in the clinic.

- We record your clinic ID, date of birth and date of clinic visit, so that the researchers can see certain clinical test results that will be matched to your survey answers. They will also see your postcode so that they can understand the answers you give in the context of where you live. However, they cannot see any of your other personal information, like your name or address.

- If you have any questions or need any help, please ask the person who gave you this survey.

- Please place your completed survey in the envelope, seal the envelope and put in the box at reception, or give it back to the staff member who gave it to you.

Thank you for your help!
Dr. Monica Desai (Mortimer Market Centre & University College London)

CONSENT

Having read the information opposite, do you agree to participate in this study?

◯ Yes   ◯ No   → Thank you for your time. Please hand this blank survey to clinic reception

SECTION A: ELIGIBILITY AND ATTENDANCE

A1. Have you completed this questionnaire before?

◯ No   ◯ Yes   → Please do not complete it again. Please hand it to clinic reception

A2. What is your gender?

◯ Male   ◯ Female → This survey is for men only. If you are not male, please do not complete it. Please place it in the box at reception

◯ Transgender (female->male)

A3. Have you ever had sex with a man? By sex, we mean oral or anal sex.

◯ Yes   ◯ No   → This survey is for men who had sex with men only. If you have never had sex with a man, please do not complete it. Please place it in the box at reception

A4. Are you HIV positive?

◯ No   ◯ Yes   → This survey is for HIV negative men only. If you are HIV positive, please do not complete it. Please place it in the box at reception

A5. Are you attending the clinic today because you have been reminded to have a sexual health consultation?

◯ No   ◯ Yes → How were you reminded?:

◯ By text message

◯ Advised by the clinician on my last visit to come back for a test for HIV and sexually transmitted infections

◯ Called by the clinic to attend for a sexual health consultation

◯ Other, please specify ---

SECTION B: SEXUAL HEALTH

We ask about your sexual health (HIV and sexually transmitted infections). Please answer as accurately as possible. Your answers will not be seen by anyone involved in your care.

B1. Are you having an HIV test today?

◯ Yes   ◯ No   ◯ Do not know yet

B2. Have you ever had an HIV test before (EXCLUDING TODAY)?

◯ YES in the last 12 months → How many times in the last 12 months? _____

◯ YES 1-2 years ago   ◯ YES more than 2 years ago

◯ NO → **If no, go to question B4**

B3. Where did you go for your last HIV test?

◯ GP   ◯ Tested at home with a home sampling kit

◯ Mortimer Market Centre (**THIS** clinic)   ◯ A **DIFFERENT** NHS Sexual Health clinic

◯ Rapid test centre (e.g.Terrence Higgins)   ◯ Private clinic

◯ Accident & Emergency (A&E)   ◯ Other, please specify _____

B4. Are you having a test for sexually transmitted infections other than HIV today (e.g. gonorrhoea, syphilis, chlamydia, hepatitis etc)?

◯ Yes   ◯ No   ◯ Do not know yet

B5. Have you ever had a test for sexually transmitted infections before (EXCLUDING TODAY)?

◯ YES in the last 12 months → How many times in the last 12 months? _____

◯ YES 1-2 years ago   ◯ YES more than 2 years ago

◯ NO → **If no, go to question C1**

B6. In the PAST 12 MONTHS (EXCLUDING TODAY), have you been diagnosed with any of the following sexually transmitted infections?

◯ Syphilis   ◯ Hepatitis C   ◯ Gonorrhoea

◯ LGV   ◯ Chlamydia   ◯ Hepatitis B

◯ I can't remember the name of the sexually transmitted infection I was diagnosed with

◯ I have never had a sexually transmitted infection

◯ Other _____

SECTION C: LIFESTYLE

We ask about your sexual lifestyle. Please answer as honestly as possible. We use 'anal sex' to mean sex where one partner puts his penis into the other partner's anus, whether or not this occurs to ejaculation.

C1. Have you EVER had ANAL sex with a man (either top/bottom/versatile), either WITH or WITHOUT a condom?

○ Yes   ○ No → **If no, go to question D1**

REGULAR MALE PARTNER

By 'REGULAR male partner' we mean boyfriends or husbands that means you are not 'single', but not partners who are simply sex buddies.

C2. Do you currently have a REGULAR male partner?

○ Yes → For how long? .... years .... months

○ No → **If no, go to question C6**

C3. Do you know your current REGULAR male partner's HIV status?

○ YES, HIV negative   ○ YES, HIV positive   ○ I don't know his status

C4. In the past 3 MONTHS, have you had anal sex (either top/bottom/versatile) WITHOUT a condom with a REGULAR male partner?

○ Yes   ○ No → **If no, go to question C6**

C5. In the past 3 MONTHS, when you had anal sex with a REGULAR male partner WITHOUT a condom, were you…? (tick ONE only)

○ Always top   ○ Mostly top

○ Always bottom   ○ Mostly bottom

○ Versatile- equally top and bottom

CASUAL MALE PARTNERS

By 'CASUAL male partner' we mean men you have had sex with once only, and men you have sex with more than once but who you don't think of as a regular partner. This includes one-night stands, anonymous and casual partners, regular sex buddies.

C6. In the past 3 MONTHS, how many different CASUAL male partners have you had anal sex with (either top/bottom/versatile) WITH or WITHOUT a condom? Please estimate if you are unsure.

Number _____

C7. In the past 3 MONTHS, have you had anal sex (either top/bottom/versatile) WITHOUT a condom with a CASUAL male partner?

◯ Yes   ◯ No → **If no, go to question D1**

C8. In the past 3 MONTHS, when you had anal sex with CASUAL male partners WITHOUT a condom, were you…? (tick ONE only)

◯ Always top   ◯ Mostly top
◯ Always bottom   ◯ Mostly bottom
◯ Versatile-equally top and bottom

C9. In the past 3 MONTHS, with how many different CASUAL male partners were you the BOTTOM sex partner WITHOUT a condom? Please estimate if you are unsure.

Number _____ → **If zero, go to question D1**

Of these, how many did you:

◯ Know to be HIV positive   _____
◯ Know to be HIV negative   _____
◯ Did not know their HIV status _____

SECTION D: Your views on being reminded to return for a HIV test and sexual health screen

HIV AND STI TESTING FREQUENCY

D1. In the UK, it is recommended that gay and bisexual men should be tested for HIV at least every 12 months. Do you agree with this recommendation?

◯ Strongly agree   ◯ Tend to agree   ◯ Undecided or no opinion

◯ Tend to disagree

◯ Strongly disagree } → If you tend to disagree/ strongly disagree, why is this? _____

_____

D2. Do YOU test for HIV and sexually transmitted infections as often as you would like to?

◯ Yes   ◯ No

D3. How often would YOU want to be tested for HIV and sexually transmitted infections at the moment? (you may tick more than one answer)

◯ Every month   ◯ Every 3 months   ◯ Every 6 months

◯ Every 12 months   ◯ After every new partner

◯ Other, please specify _____

D4. Here are some statements about regular HIV and STI testing. Please read each statement carefully and place a tick in the box that is closest to your viewpoint. Give only one answer for each row.

	Strongly agree	Tend to agree	Undecided or no opinion	Tend to disagree	Strongly disagree
a) I believe that I am at risk of becoming infected with HIV					
b) Fear of a positive test result puts me off testing					
c) I don't want to put others at risk of HIV					
d) Most of my gay friends test regularly for HIV					

TESTING REMINDERS FOR HIV & SEXUALLY TRANSMITTED INFECTIONS

D5. If you were to receive a reminder to be tested for HIV and sexually transmitted infections regularly, which type of reminder would you prefer? (you can tick more than one)

◯ Text message   ◯ Phone call
◯ Letter   ◯ Email
◯ Test sent to my home ◯ I do not want a reminder
◯ Other, please specify --

D6. Here are some statements about testing reminders for HIV and sexually transmitted infections. Please read each statement carefully and place a tick in the box that is closest to your viewpoint. Give only one answer for each row.

	Strongly agree	Tend to agree	Undecided or no opinion	Tend to disagree	Strongly disagree
a) I like being reminded to check my health status					
b) I am concerned that a reminder to have a test for HIV and sexually transmitted infections would breach my confidentiality					
c) I am concerned that receiving a reminder to have a test for HIV and sexually transmitted infections would stigmatise me					

D7. If you were sent a reminder to have a test for HIV and sexually transmitted infections, how likely are you to have the test?

◯ Extremely likely ◯ Quite likely ◯ Not very likely ◯ Extremely unlikely

D8. How often would you want to receive a REMINDER to have a test for HIV and sexually transmitted infections? (tick ONE only)

◯ Every 3 months   ◯ Every 6 months   ◯ Once a year
◯ I do not want a reminder ◯ Other, please specify --

D9. Which of the following would make you more likely to test for HIV and sexually transmitted infections? (you can tick more than one)

- ◯ Receiving a reminder to test
- ◯ Recent unprotected anal sex with a casual partner
- ◯ Receiving a STI and HIV home sampling kit at my clinic visit for future use
- ◯ Receiving a STI and HIV home sampling kit in the post
- ◯ Other, please specify ....

....

TESTING VENUES FOR HIV & SEXUALLY TRANSMITTED INFECTIONS

In this question, home sampling refers to receiving a test for HIV or sexually transmitted infections in the post to an address of your choice. You are given simple instructions to follow to take the test and you then send the test back in the post to a laboratory. You are informed of the test results at a later stage, not on the same day.

D10. Where would you want to go for a regular test for HIV and sexually transmitted infections? (you can tick more than one)

- ◯ GP
- ◯ NHS Sexual Health/GUM clinic
- ◯ Private sexual health clinic
- ◯ Other, please specify ....
- ◯ Test at home with a home sampling kit
- ◯ Rapid test centre (e.g. Terrence Higgins Trust)
- ◯ Accident & Emergency (A&E)

D11. Which of the following factors are important to you when deciding where to have a regular test for HIV and sexually transmitted infections? (you can tick more than one)

- ◯ Proximity of the clinic to place of work/home
- ◯ Confidentiality of the service
- ◯ A personal recommendation
- ◯ Option to home sample
- ◯ Shorter waiting times
- ◯ Other, please specify ....
- ◯ After hours service
- ◯ Weekend opening
- ◯ Same day results
- ◯ Previous use of clinic

D12. Would you prefer to see a clinician at a NHS Sexual Health/GUM clinic or receive a home sampling kit to test for HIV and sexually transmitted infections? (tick ONE only)

- ◯ See a clinician
- ◯ Test at home with a home sampling kit

SECTION E: DEMOGRAPHICS

E1. Which ethnic group best describes you? (tick ONE only)

◯ White   ◯ Black (Africa/Caribbean/Other)

◯ South East Asian   ◯ Asian (Indian/Pakistani/Bengali)

◯ Mixed/Other, please specify ....

E2. Were you born in the UK?

◯ Yes → **go to question E3**

◯ No → **which country were you born in?** ....

→ **When did you first move to the UK?**

◯ Less than 1 year ago   ◯ 1 to 5 years ago   ◯ More than 5 years ago

E3. Which of the following best describes your MAIN current occupation? (tick ONE only)

◯ Employed full-time   ◯ Employed part-time

◯ Self-employed   ◯ Unemployed

◯ Student   ◯ Retired

◯ Long-term sick leave/medically retired

◯ Other, please specify ....

E4. At what level did you COMPLETE your education?

◯ Still in full-time or part-time education   ◯ A levels (or equivalent at age 18

◯ Finished education with no qualifications   ◯ University degree or above

◯ O levels/GCSEs (or equivalent at age 16)

◯ Other qualifications, please specify ....

E4. Which of the following options best describes how you think of yourself?

◯ Heterosexual/straight   ◯ Gay

◯ Bisexual   ◯ Other, please specify ....

We would like to have a longer discussion to explore some of the issues around testing reminders for HIV and sexually transmitted infections. Would you be willing to participate in a one hour interview?

We will only be contacting a small number of participants. By answering 'yes' to this question, you agree to us accessing your contact details from the Mortimer Market clinic database to invite you for interview.

◯ Yes   ◯ No

We would welcome any feedback you have on this survey. Please use this space to tell us anything you think could be improved.

Thank you very much for completing this survey. Please remember to tick the consent box on the front page before handing in your completed survey.

Please seal the survey in the envelope provided and put it in the box at reception.

Thank you.

Further information about HIV and AIDS and sexually transmitted infections is available from:

THT DIRECT HELPLINE: 0845 122 1200

From 10am to 10pm Monday to Friday & 12pm to 6pm Saturday & Sunday. Telephone advice, information and support service about HIV and AIDS information can also be found on the Terence Higgins Trust website at: **www.tht.org.uk**

THIS PROJECT IS RUN BY:
Research Department of Infection and Population Health, University College London, in collaboration with Mortimer Market Centre, Central and Northwest London NHS Foundation Trust

Contact for any queries:
Monica Desai, University College London
Email: **m.desai.12@ucl.ac.uk**

Study No. ☐☐☐☐☐ (Office use only)

4.4 Survey questions measuring Theory of Planned Behaviour constructs

TPB construct	Question	Cronbach's alpha
Attitude to HIV testing	D4 (b): Fear of a positive test result puts me off testing D4 (c): I don't want to put others at risk of HIV	0.03
Social norm of HIV testing	D4 (d): Most of my gay friends test regularly for HIV	
Perceived behavioural control of HIV testing	D11: Which of the following factors are important to you when deciding where to have a regular test for HIV and sexually transmitted infections?	
Attitudes to reminders	D6 (a): I like being reminded to check my health status	
Social norms of reminders	Not assessed	
Perceived behavioural control of reminders	D6 (b): I am concerned that a reminder to have a test for HIV and sexually transmitted infections would breach my confidentiality D6 (c): I am concerned that a reminder to have a test for HIV and sexually transmitted infections would stigmatise me	0.72
Intention to reattend	D7: If you were sent a reminder to have a test for HIV and sexually transmitted infections, how likely are you to have the test?	

4.5 Source of evidence for survey questions

The questions stated in this table are the original survey questions; several were modified based on the findings of the cognitive interviews.

Source	Questions
Health, sex steroids (survey obtained from author)	A2: Have you ever had sex with a man B2: Have you ever had an HIV test before B3: Where did you go for your last HIV test C4: In the past 3 months, when you had anal sex with non-steady male partners without a condom, were you…? D1: In the UK, it is recommended that gay and bisexual men should be tested for HIV every 12 months. Do you agree with this recommendation? D4a: I don't believe that I am at risk of HIV D4b: Fear of a positive test result puts me off being tested D4c: I don't want to put others at risk D5: Where would you want to go for a regular HIV and STI test? (options from health, sex steroids survey)
ASTRA(317)	A3: Are you HIV positive? E2: Were you born in the UK? E4: At what level did you complete your education?
EMIS(318)	C1: Have you ever had anal sex with a man (either 'receptive/bottom' or 'insertive/top'), either with or without a condom C2: In the past 3 months, how many different non-steady male partners have you had anal sex with (either 'receptive/bottom' or 'insertive/top') with or without a condom? C3: In the past 3 months, have you had anal sex (either 'receptive/bottom' or 'insertive/top') without a condom with a non-steady male partner? C8: In the past 3 months, how many different steady male partners have you had anal sex with (either 'receptive/bottom' or 'insertive/top') with or without a condom? C9: In the past 3 months, have you had anal sex (either

	'receptive/bottom' or 'insertive/top') without a condom with a steady male partner? E3: Which of the following best describes your current occupation? E5: Which of the following options best describes how you think of yourself?
Sexual health survey of men 2008 (survey obtained from author)	In the past 3 months, with how many different non-steady male partners were you the receptive/bottom sex partner without a condom?
ONS(319)	E1: Which ethnic group best describes you

4.6 Survey results tables

Table 23: Reason for attendance: overall and proportion intending to reattend compared to proportion not intending to reattend

	Distribution in survey sample (N=394) *Column percentage*	Intending to reattend if sent a reminder (N=351) *Row percentage*	Association with intention to reattend: P value
Returning to clinic due to reminder	75 (19%)	69 (100%)	**0.012***
Attending clinic not due to a reminder	319 (81%)	282 (92%)	
Missing	12	10	

Table 24: Respondent demographics compared to MSM attending genitourinary medicine clinics in England (GUMCAD data)

	Number (%) (N= 397)	HIV negative/unknown status MSM attending GUM clinics in England 2013 (GUMCAD) (N=92,037)	P value[24]
Age	Median 34 (95% CI 32-35)		
<20	8 (2.7%)	4446 (5%)	**0.004**
20-24	34 (11%)	16887 (18%)	
25-34	124 (41%)	33829 (37%)	
35-44	77 (26%)	19425 (21%)	
45-64	53 (18%)	15517 (17%)	
>64	3 (1%)	1918 (2%)	
Missing[25]	98		
Ethnicity			
White	326 (83%)	73707 (80%)	0.567
Black (African/Caribbean/Other)	17 (4%)	3049 (3%)	
South East Asian	8 (2%)	4022 (4%)	
Asian (Indian/Pakistani/Bengali)	8 (2%)	Asian/SE Asian one category	
Mixed/Other	35 (9%)	6617 (7%)	
Missing	12	Not specified (5%)	
Born in UK			
Yes	205 (52%)	62364 (68%)	**<0.001**
No	190 (48%)	24045 (26%)	
Missing	11	unknown: 6%	

---

[24] Fisher's exact where cells contain <5 observations. Chi2 test where >=5 observations
[25] Missing values are not included in the column percentages

Table 25: Log odds of being likely to return for a test if sent a reminder (binary logistic regression)

Explanatory variable	Univariable binary OR	p value	Multivariable binary logistic OR[26]	Multivariable p value
Returning to clinic due to reminder	N/A	N/A		
DEMOGRAPHICS				
Age				
18-25	1			
25-30	0.00	0.990		
30-35	0.00	0.991		
35-40	0.00	0.990		
40-45	0.00	0.990		
45-50	0.00	0.990		
>50	0.00	0.989		
Ethnicity				
White	1			
Black (African/Caribbean/Other)	0.57	0.644		
South East Asian	1.21	0.870		
Asian (Indian/Pakistani/Bengali)	0.57	0.644		
Other/mixed	1.12	0.781		
Born in UK				
No				
Yes	0.00	0.991		
Occupation				
Other	1			
Employed full-time	0.92	0.934		
Employed part-time	0.43	0.510		
Long-term sick/medically retired	1.00			
Retired	0.32	0.382		
Self-employed	1.45	0.754		
Student	2.71	0.491		
Unemployed	1.00			

---

[26] Multivariable OR are only presented for variables included in the final parsimonious model

Education				
Other	1			
A-levels	0.00	0.992		
Finished education with no qualifications	0.00	0.991		
O Levels/GCSEs	1.00			
In full/part-time education	1.00			
University degree or above	0.00	0.992		
SEXUAL HEALTH				
Having a HIV test today				
Yes	1	**0.176**		
No	0.34	0.757		
Don't know yet	0.79			
Ever had an HIV test before				
No	1			
Yes 1-2 years ago	9.40	**0.078**		
Yes, in last 12 months	2.68	0.223		
Yes >2 years ago	1.6	0.663		
If tested in the past 12 months, number of HIV tests	1.01	0.943		
Where did you go for your last HIV test?				
A different NHS sexual health clinic	1			
A+E	1.2	0.769		
GP	1			
This sexual health clinic	1			
Private clinic	1.5	0.488		
Rapid test centre	1			
Home sampling kit	1			
Other	1			
Having an STI test today				
Yes	2.43	0.091		
No	1.12	0.837		

Don't know yet	1			
Ever had an STI test before				
Yes, in last 12 months	0.83	0.857		
Yes 1-2 years ago	1			
Yes >2 years ago	0.24	0.204		
No	1			
If tested in the past 12 months, number of STI tests				
STIs diagnosed in past 12 months				
Syphilis	1			
HCV	1			
Gonorrhoea	3.04	0.137		
LGV	-			
Chlamydia	0.56	0.237		
HBV	1			
Can't remember the name	1			
Never had an STI	0.77	0.340		
Other				
Ever had anal sex with man				
Yes	1			
No	0.00	0.994		
REGULAR MALE PARTNER				
Has RMP				
Yes	1.28	0.554		
No	1			
Time with RMP				
RMP HIV status				
Known and HIV positive	2.51	0.276		
Known and HIV negative	1			
Do not know status	1			
UAI with RMP in past 3 months				
Yes	2.12	0.242		

No	1			
Sexual position when UAI with RMP in past 3 months				
Always top	1			
Mostly top	1			
Always bottom	1			
Mostly bottom	1			
Versatile	2.58	0.369		
CASUAL MALE PARTNER				
Number of different CMP in past 3 months				
UAI with CMP in past 3 months				
Yes	1.31	0.61		
No	1			
Sexual position when UAI with CMP in past 3 months				
Always top	0.68	0.748		
Mostly top	1			
Always bottom	1			
Mostly bottom	0.37	0.440		
Versatile	1.35	0.835		
HIV AND STI TESTING FREQUENCY				
Agreement with national HIV testing guidelines (12 months testing)				
Strongly agree	1			
Tend to agree	0.09	**<0.001**	0.06	**<0.001**
Undecided	0.11	**0.011**	0.15	0.143
Tend to disagree	0.41	0.281	0.32	0.234
Strongly disagree	0.19	0.056	0.11	**0.048**
Agree (strongly/tend to)	1			

Disagree (strongly/tend to/undecided)	0.56	0.241		
Test as often as would like to				
Yes	0.99	0.989		
No	1			
Preferred frequency of testing (can pick more than one option)				
Every month	1.08	0.939		
Every 3 months	1.58	0.296		
Every 6 months	1.56	0.354		
Every 12 months	1.30	0.640		
After every new partner	0.52	0.251		
Attitudes to regular HIV testing *Believe at risk of becoming infected with HIV*				
Strongly agree	1			
Tend to agree	0.28	0.240		
Undecided	0.66	0.720		
Tend to disagree	0.65	0.696		
Strongly disagree	0.20	0.148		
Agree (strongly/tend to)	0.79	0.568		
Disagree (strongly/tend to/undecided)	1			
Fear of positive tests puts me off testing				
Strongly agree	1			
Tend to agree	1.07	0.928		
Undecided	2.20	0.405		
Tend to disagree	1.65	0.512		
Strongly disagree	1.54	0.528		
Agree (strongly/tend to)	0.64	0.308		
Disagree (strongly/tend to/undecided)	1			

Don't want to put others at risk				
Strongly agree	1			
Tend to agree	0.82	0.799		
Undecided	0.55	0.579		
Tend to disagree	0.07	0.061		
Strongly disagree	1			
Missing				
Agree (strongly/tend to)	2.05	0.359		
Disagree (strongly/tend to/undecided)	1			
Most gay friends test for HIV regularly				
Strongly agree	1			
Tend to agree	0.89	0.855		
Undecided	0.37	0.196		
Tend to disagree	0.54	0.547		
Strongly disagree	0.31	0.358		
Agree (strongly/tend to)	2.35	0.056		
Disagree (strongly/tend to/undecided)	1			
TESTING REMINDERS FOR HIV & STIs				
Reminder preference (can pick more than one option)				
SMS	14.63	**0.000**	26.83	**0.000**
Phone call	0.55	0.452		
Email	4.41	**0.047**	21.54	**0.001**
Home sampling	0.57	0.386		
Don't want a reminder	0.04	**0.000**		
Attitudes to testing reminders				
Like being reminded to check health status				
Strongly agree	1			

Tend to agree	0.00	0.996		
Undecided	0.00	0.995		
Tend to disagree	0.00	0.995		
Strongly disagree	0.00	0.994		
Agree (strongly/tend to)	56.19	**0.000**		
Disagree (strongly/tend to/undecided)	1		0.55	**0.007**
Concerned about confidentiality of reminders				
Strongly agree	1			
Tend to agree	0.00	0.990		
Undecided	0.00	0.991		
Tend to disagree	0.00	0.992		
Strongly disagree	0.00	0.992		
Agree (strongly/tend to)	0.28	**0.002**		
Disagree (strongly/tend to/undecided)	1			
Concerned about being stigmatised for receiving a reminder				
Strongly agree	1			
Tend to agree	0.00	0.987		
Undecided	0.00	0.989		
Tend to disagree	0.00	0.988		
Strongly disagree	0.00	0.989		
Agree (strongly/tend to)	0.20	**0.000**		
Disagree (strongly/tend to/undecided)	1		1.48	**0.080**
Preferred reminder frequency (can pick more than one option)				
Every 3 months	1			
Every 6 months	11.58	**0.019**		
Once a year	3.00	0.233		

Don't' want a reminder	0.14	0.019		
Factors that would increase likelihood of testing (can pick more than one option)				
Reminder to test	39.93	**0.000**		
Recent UAI with CMP	0.34	**0.054**		
Home sampling kit given at clinic visit for future use	0.59	0.235		
Home sampling kit sent in post	1.46	0.429		
TESTING VENUES FOR HIV & STIs				
Preferred venue to HIV/STI test (can pick more than one option)				
GP	1.97	0.365		
Home sampling	1.31	0.535		
NHS GUM clinic	1.87	0.203		
Rapid test centre	0.77	0.551		
Private sexual health clinic	1.15	0.828		
A+E	1			
Important factors in deciding where to have regular test for HIV/STI (can pick more than one option)				
Proximity of clinic	0.54	0.197		
After hours service	1.14	0.756		
Confidentiality of service	1.96	0.101		
Weekend opening	0.78	0.546		
Personal recommendation	1.91	0.303		
Same day results	1.03	0.943		
Option to home sample	4.30	0.157		
Previous use of clinic				
Shorter waiting times				
Other				
Prefer to see clinician				

or home sample				
Clinician	2.51	0.142		
Home sample	1			
Missing				

Table 26: Regression analysis of attitudes to testing and documented reattendance among those sent a reminder

Explanatory variable	Adjusted Binary univariate logistic regression OR[27]	p-value	Adjusted Binary multivariate logistic regression OR[28]	p-value
Agreement with national HIV testing guidelines (12 months testing)				
Agree (strongly/tend to)	REF			
Disagree (strongly/tend to/undecided)	2.518	0.153	n/a	n/a
Attitudes to regular HIV testing				
Believe at risk of becoming infected with HIV				
Agree (strongly/tend to)	1.227	0.131	1.865	0.374
Disagree (strongly/tend to/undecided)	REF			
Fear of positive tests puts me off testing				
Agree (strongly/tend to)	0.050	**0.019***	0.653	0.697
Disagree (strongly/tend to/undecided)	REF			
Don't want to put others at risk				
Agree (strongly/tend to)	0.474	0.579	1.525	0.801

[27] Adjusted for demographics (age, ethnicity, born in UK, occupation, education) and UAI with CMP
[28] Adjusted for UAI with RMP, UAI with CMP, STI test today, gonorrhea, agreement with HIV test guidelines, reminder preference, reminder frequency. Univariable covariates with p<0.2 included in final multivariable model.
* Covariates with p<0.2 in the univariable model were assessed for inclusion in the final multivariable model

Disagree (strongly/tend to/undecided)	REF			
Most gay friends test for HIV regularly		0.484		
Agree (strongly/tend to)	1.510		2.574	0.211
Disagree (strongly/tend to/undecided)	REF			
Attitudes to testing reminders				
Like being reminded to check health status	5.357	0.134	7.990	0.085
Agree (strongly/tend to)	REF			
Disagree (strongly/tend to/undecided)				
Concerned about confidentiality of reminders				
Agree (strongly/tend to)	0.283	**0.002***	1.332	0.823
Disagree (strongly/tend to/undecided)	REF			
Concerned about being stigmatised for receiving a reminder		0.394		
Agree (strongly/tend to)	0.340		1	0.998
Disagree (strongly/tend to/undecided)	REF			

5. In-depth interviews

5.1 Patient information sheet for in-depth interviews

Central and North West London **NHS**
NHS Foundation Trust

Camden Provider Services

PARTICIPANT INFORMATION SHEET

Drivers and barriers to active recall for HIV testing of men who have sex with men at high risk of HIV infection in Genitourinary Medicine clinics: one-to-one discussion

1. What is the purpose of the study?

We would like to find out more about what encourages or deters gay or homosexual men from being reminded to have regular tests for HIV and sexually transmitted infections (STIs). We are inviting you to take part in a face-to-face discussion to explore these issues. The discussions will be interactive, and you will be encouraged to talk freely.

2. Why have I been invited?

We want to talk to sixteen gay or homosexual men. The research team will select a small number of participants from those who said that they were willing to participate in the discussions in the questionnaire that you have completed on the same topic. This is to make sure that we interview a representative sample of our clinic population.

3. What will I have to do?

If you are selected for the discussions, the researcher will use the clinic ID and date of birth that you provided on the questionnaire to request your contact phone number from the clinic. They will not access your clinical details. The researcher will send you a text message asking you to contact them to arrange a suitable time for the discussion.

You will have the conversation with the researcher in a private clinic room at the Mortimer Market Clinic. The whole conversation will **last approximately one hour**. The conversation will be audio recorded so that the research team can review your answers. You will have the opportunity to ask any further questions about the study at before the discussion begins and you will be asked to sign a consent form at the start of the discussion.

4. Will I be paid to take part?

You will receive a high street voucher as a small compensation for your time. You will also be able to claim reasonable travel expenses up to a value of £10. Some refreshments will be provided during the discussion.

5. What will happen if I don't want to carry on with the study?

IDI!PIS!v06!6th!February!2014!

You do not have to join if you do not want to. If you change your mind during the cognitive interview study you can withdraw at any time with or without giving a reason.

If you withdraw from the one-to-one discussion study, any information that could be linked back to you will be destroyed. However, any information that you have already provided that cannot be linked back to you will be used in the study analysis.

Deciding not to take part in the study will not affect your medical care.

6. What are the possible risks of taking part?

There is no risk to you taking part in this study. If you find that the discussion raises issues that you would like to discuss further, please ask the researcher to arrange for you to speak to one of the investigators.

7. What if something goes wrong?

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the Camden Provider Services but you may have to pay your legal costs. The normal National Health Service complaints mechanism will still be available to you.

8. Will my responses be confidential?

Nobody outside of the research group and clinicians will know that you are taking part in the study.

The research team will only access the contact details of those participants they invite to take part in the discussions. They will use the clinic ID and date of birth that you provided in the questionnaire to access your contact telephone number from the clinic database held at Mortimer Market Clinic.

For the discussion recordings, anything that could identify you will be removed from the audio recording. You will only be identified by your study number. A specially trained researcher will listen to and analyse all the discussions.
The audio recording will be stored in a secure site in the research office.

Data will be stored in accordance with the Data Protection Act 1998 and NHS Regulations for 3 years, after which time it will be disposed of securely.

The data collected may be used for additional related research after approval from the Research Ethics Committee.

9. What will happen to the results of the research study?

The results of the one-to-one discussions will be in an internal report and in peer reviewed publications. You will not be identified in the results of the study that are published.

10. Who is organizing the study?

This study is being organised by University College London and Public Health England and is sponsored and insured by Central and North West London NHS Foundation Trust. The study is funded by the British HIV Association.

IDI!PIS!v06!6th!February!2014!

11. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Leeds West Research Ethics Committee (ref: 13/YH/0347).

12. Who should I talk to if I have more questions?

If you have more questions about any aspect of this study, please contact a member of the research team on 0203 108 2361.

If you have any concerns and wish to complain formally, you can do this by contacting patientsupport.cps@nhs.net.

Thank you for taking the time to read this information sheet and considering the study.

!

5.2 Topic guide

Recall study: Topic guide for one-to-one discussion

Introduction

- · Introduce self and role
- · Check read information sheet
- · Aim of study and funder
- · How interview will work
- · Audio recording
- · Confidentiality, anonymity
- · Withdrawal and refusal to answer questions
- · Result dissemination
- · Incentive payment
- · Any further questions

Discussion topics:

1. **BACKGROUND**

Aim: To understand the background context of the respondent, in particular less than regular lifestyles

    a. Ask about self, work and working patterns

2. **SEXUAL RISK AND LIFESTYLE**

Aim: To explore context of sexual risk, unprotected sex, and sexual risk and sexual networks

    a. Current partnerships
        i. Regular
        ii. Casual
    b. Partnerships in past 3 months
        i. Regular
        ii. Casual
    c. Sexual risk in general
        i. Condomless/with condom and types of sex
        ii. Chem sex
        iii. Where meets partners

3. **HIV TESTING PATTERNS**

Aim: To explore testing patterns, and regularity and reasons for testing for HIV infection

    a. How many times tested in past year
    b. Reasons for testing
    c. Explore regular versus repeat testing
    d. How often would they want to have an HIV test
        i. Explore based on different risk profiles

4. **REMINDERS**

Aims: To explore experience with healthcare reminders

   a. What does 'reminder' mean to the respondent in the context of HIV/STI screening?
   b. Have they ever received a reminder to return for an HIV/STI test or for any other healthcare appointment?
   c. If yes,
      i. what kind of reminder?
      ii. What were their views on the reminder? Probe acceptability and barriers fully
   d. If no, what are their attitudes to reminders for HIV/STI testing?
      i. Probe potential drivers and barriers fully
         1. Confidentiality, stigma, routine health checks,
   e. Types of reminder and associated acceptability and barriers
      i. Explore SMS, email, letter, postcard, phone call, home sampling

5. **INTENTION**

Aim: To explore intention to test if sent a reminder and what types/frequency would facilitate/hinder restest

   a. Would they return if sent a reminder?
   b. If yes, why? If no, why not?
   c. What would make them more likely to return?
      i. Explore timing, types of reminder, associated sexual risk, retesting venue or mode (e.g. home sampling)
      ii. Convenience factors- availability of testing facilities, access to result
      iii. Perceived behavioural control- barriers to return or enabling factors
   d. Do they feel that they need a reminder/would a reminder be beneficial? What would be the hindering factors associated with a reminder?

6. **RECOMMENDATIONS**
   a. Recommendations for methods of reminding
      i. Type of reminder
         1. Explore practicalities and reasons for that reminder choice and whether more than one type for different scenarios
      ii. Frequency of reminder
         1. Explore whether different frequencies and what base on (e.g. risk)
      iii. When a reminder would be of use and when not

7. **CONCLUSION**
   a. Thank participant
   b. Reiterate confidentiality and anonymity
   c. Incentive
   d. Stop audio recording

5.3 Consent form

Central and North West London **NHS**
NHS Foundation Trust

Camden Provider Services

Research title: Drivers and barriers to active recall for HIV testing of MSM at high risk of HIV infection in Genitourinary Medicine clinics: one-to-one discussion

Patient identification number ……………………………...

Name of person taking consent ……………………………...

Contact details of person taking consent ……………………………..

PLEASE INITIAL BOXES

1. I confirm that I have read and understand the information sheet dated 19th November 2013 (version 0.5) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that the discussion will be audio recorded and that delegated members of the research team will listen to the tape to either transcribe or analyse the discussion. I give permission for the discussion to be audio recorded and for delegated members of the research team to have access to the audio recording, or transcription of it, and for verbatim quotations to be used in the study reports, but understand that my confidentiality will be maintained.

4. I understand that any of my study notes, including audio or written files of the discussion, may be looked at or listened to by responsible individuals from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records, but understand that my confidentiality will be maintained.

5. I understand that relevant sections of data collected during the study, may be looked at by individuals from the sponsor of the trial (Central and Northwest London NHS Foundation Trust) and responsible persons authorised by the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

6. I understand that the data collected in this study may be used in future ethically approved studies

7. I agree to take part in the above study.

_____   _____   _____
Name of Participant   Date (dd/mm/yyy)   Signature

_____   _____   _____
Name of Researcher   Date (dd/mm/yyyy) Signature

_____   _____   _____
Name of person asking for consent   Date (dd/mm/yyyy)   Signature
(if different to the person taking consent)

When completed: 1 for participant; 1 (original) for researcher site file; 1 to be kept in medical notes.

IDI consent v 0.3 22nd Jan 2014

6. Publications

Desai M, Woodhall SC, Nardone A, Burns F, Mercey D, Gilson R. Active recall to increase HIV and STI testing: a systematic review. Sex Transm Infect 2015; **0**: 1-10.

References

1.   Yin Z BA, Hughes G, Nardone A, Gill ON, Delpech VC & contributors. HIV in the United Kingdom 2014 Report: data to end 2013. In: Public Health England, editor. London2014.

2.   Birrell PJ, Gill ON, Delpech VC, Brown AE, Desai S, Chadborn TR, et al. HIV incidence in men who have sex with men in England and Wales 2001-10: a nationwide population study. Lancet Infect Dis. 2013;13(4):313-8.

3.   British Association of Sexual Health and HIV. Recommendations for testing for sexually transmitted infections in men who have sex with men. 2014.

4.   Hutchinson AB, Sansom, S.L., Farnham, P.G., Lin, F. . Cost-effectiveness of more frequent HIV screening of MSM in the United States XIX International AIDS Conference July 22-27 2012 Washington DC, USA 2012.

5.   Gray RT, Prestage GP, Down I, Ghaus MH, Hoare A, Bradley J, et al. Increased HIV testing will modestly reduce HIV incidence among gay men in NSW and would be acceptable if HIV testing becomes convenient. PLoS One. 2013;8(2):e55449.

6.   McDaid L, Aghaizu A, Frankis J, Riddell J, Nardone A, Mercey D, Johnson AM, Hart GJ, Flowers P. Frequency of HIV testing among gay and bisexual men in the UK: implications for prevention. unpublished. 2014.

7.   Pal B, Taberner DA, Readman LP, Jones P. Why do outpatients fail to keep their clinic appointments? Results from a survey and recommended remedial actions. Int J Clin Practice 1998;52(6):436-7.

8.   Jacobson Vann J, Szilagyi P. Patient reminder and recall systems to improve immunization rates. Cochrane Database of Systematic Reviews. 2009(3).

9.   Munro HL, Lowndes CM, Daniels DG, Sullivan AK, Robinson AJ. National study of HIV testing in men who have sex with men attending genitourinary clinics in the United Kingdom. Sex Transm Infect. 2008;84(4):265-70.

10.   Ajzen I. The theory of planned behavior. Organizational Behavior and Human Decision Processes 1991;50(2):179–211.

11.   World Health Organisation. HIV/AIDS Fact Sheet 2014 [cited 2015 3rd April]. Available from: http://www.who.int/mediacentre/factsheets/fs360/en/.

12.   UNAIDS. Global Report: UNAIDS report on the global AIDS epidemic 2013 Geneva, Switzerland: 2013.

13.   Gregson S, Gonese E, Hallett TB, Taruberekera N, Hargrove JW, Lopman B, et al. HIV decline in Zimbabwe due to reductions in risky sex? Evidence from a comprehensive epidemiological review. Int J Epidemiol. 2010;39(5):1311-23.

14.   Halperin DT, Mugurungi O, Hallett TB, Muchini B, Campbell B, Magure T, et al. A surprising prevention success: why did the HIV epidemic decline in Zimbabwe? PLoS Med. 2011;8(2):e1000414.

15.   Johnson LF, Hallett TB, Rehle TM, Dorrington RE. The effect of changes in condom usage and antiretroviral treatment coverage on human immunodeficiency virus incidence in South Africa: a model-based analysis. J R Soc Interface. 2012;9(72):1544-54.

16.	The Global Fund. Fighting AIDS Geneva, Switerland 2013 [cited 2013 30th December]. Available from:
http://www.theglobalfund.org/en/about/diseases/hivaids.
17.	Abrams EJ, Myer L. Can we achieve an AIDS-free generation? Perspectives on the global campaign to eliminate new pediatric HIV infections. J Acquir Immune Defic Syndr. 2013;63 Suppl 2:S208-12.
18.	Wettstein C, Mugglin C, Egger M, Blaser N, Vizcaya LS, Estill J, et al. Missed opportunities to prevent mother-to-child-transmission: systematic review and meta-analysis. AIDS. 2012;26(18):2361-73.
19.	World Health Organisation. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach Geneva, Switzerland World Health Organisation,. 2013.
20.	Health Protection Agency HIV in the United Kingdom: 2012 Report Colindale, London 2012.
21.	Aghaizu A BA, Nardone A, Gill ON, Delpech VC & contributors. . HIV in the United Kingdom 2013 Report: data to end 2012 Public Health England, London., 2013.
22.	British HIV Association. Standards of care for people living with HIV, 2013. British HIV Association 2012.
23.	May M, Gompels M, Delpech V, Porter K, Post F, Johnson M, et al. Impact of late diagnosis and treatment on life expectancy in people with HIV-1: UK Collaborative HIV Cohort (UK CHIC) Study. BMJ. 2011;343.
24.	Halve It. Halve it position paper.
25.	Health Protection Agency Sexually transmitted infections in men who have sex with men in the UK: 2011 Report 2011.
26.	Presanis AM, DeAngelis, D., Goubar, A., Gill, O.N., Ades, A.E. . Bayesian evidence synthesis for a transmission dynamic model for HIV among men who have sex with men Biostatistics. 2011;1:1-28.
27.	Lattimore S, Thornton A, Delpech V, Elford J. Changing patterns of sexual risk behavior among London gay men: 1998-2008. Sex Transm Dis. 2011;38(3):221-9.
28.	Hickson F, Bourne A, Weatherburn P, Reid D, Jessup K, Hammond G . Tactical dangers: findings from the United Kingdom Gay Men's Sex Survey 2008 2008.
29.	Savage EJ, Marsh K, Duffell S, Ison CA, Zaman A, Hughes G. Rapid increase in gonorrhoea and syphilis diagnoses in England in 2011. Euro Surveill. 2012;17(29).
30.	Fleming DT, Wasserheit JN. From epidemiological synergy to public health policy and practice: the contribution of other sexually transmitted diseases to sexual transmission of HIV infection. Sex Transm Infect. 1999;75(1):3-17.
31.	Malek M, Mitchell H, Furegato M, Simms I, Mohammed H, Nardone A, Hughes G. Contribution of transmission in HIV-positive men who have sex with men to evolving epidemics of sexually transmitted infections in England: an analysis using multiple data sources, 2009-2013. Eurosurveillance. 2015;20(15):pii=21093.

32.   Bolding G, Davis M, Hart G, Sherr L, Elford J. Gay men who look for sex on the Internet: is there more HIV/STI risk with online partners? AIDS. 2005;19(9):961-8.

33.   Elford J, Bolding G, Sherr L. Seeking sex on the Internet and sexual risk behaviour among gay men using London gyms. AIDS. 2001;15(11):1409-15.

34.   British HIV Association BAoSHaH, British Infection Society,. . UK national guidelines for HIV testing 2008 2008

35.   National Institute for Health and Clinical Excellence. Increasing the uptake of HIV testing among men who have sex with men. London: NICE, 2011.

36.   National Institute for Health and Clinical Excellence. One to one interventions to reduce the transmission of sexually transmitted infections (STIs) including HIV, and to reduce the rate of under 18 conceptions, especially among vulnerable and at risk groups London: NICE 2007.

37.   Clutterbuck D, Flowers P, Barber T, Wilson H, Nelson M, Hedge B, et al. UK national guideline on safer sex advice. International journal of STD & AIDS. 2012;23(6):381-8.

38.   van Sighem A, Vidondo B, Glass TR, Bucher HC, Vernazza P, Gebhardt M, et al. Resurgence of HIV infection among men who have sex with men in Switzerland: mathematical modelling study. PLoS One. 2012;7(9):e44819.

39.   Brenner BG, Roger M, Routy JP, Moisi D, Ntemgwa M, Matte C, et al. High rates of forward transmission events after acute/early HIV-1 infection. J Infect Dis. 2007;195(7):951-9.

40.   Brown A, Gill O, Delpech V. HIV treatment as prevention among men who have sex with men in the UK: is transmission controlled by universal access to HIV treatment and care? HIV medicine. 2013;14(9):563-70.

41.   Brown AE, Nardone A, Delpech VC. WHO 'Treatment as Prevention' guidelines are unlikely to decrease HIV transmission in the UK unless undiagnosed HIV infections are reduced. Aids. 2014;28(2):281-3.

42.   McDaid LM, Hart GJ. Increased HIV testing and reduced undiagnosed infection among gay men in Scotland, 2005-8: support for the opt-out testing policy? Sex Transm Infect. 2011;87(3):221-4.

43.   Burns F, Hart G. Increased HIV testing in men who have sex with men. BMJ. 2012;344:e501.

44.   European Centre for Disease Prevention and Control. HIV testing: Increasing uptake and effectiveness in the European Union. Stockholm: ECDC, 2010.

45.   Department of Health. A framework for sexual health improvement In: Department of Health, editor. London2013.

46.   Imrie J, Macdonald N. HIV testing in men who have sex with men: are we ready to take the next HIV testing test? Sex Transm Infect. 2009;85(7):487-8.

47.   Beck EJ, Mandalia S, Sangha R, Sharott P, Youle M, Baily G, et al. The cost-effectiveness of early access to HIV services and starting cART in the UK 1996-2008. PLoS One. 2011;6(12):e27830.

48.   Brennan V. The case for universal testing for HIV in the UK Gilead Best Practice Sharing Event 19 May 20112011.

49.   Rotheram-Borus MJ, Lee MB, Murphy DA, Futterman D, Duan N, Birnbaum JM, et al. Efficacy of a preventive intervention for youths living with HIV. American Journal of Public Health. 2001;91(3):400-5.

50.   Centers for Disease Control and Prevention. Interim guidance on pre-exposure prophylaxis for the prevention of HIV infection in men who have sex with men. Atlanta2011.

51.   Finlayson TJ, Le B, Smith A, Bowles K, Cribbin M, Miles I, et al. HIV risk, prevention, and testing behaviors among men who have sex with men--National HIV Behavioral Surveillance System, 21 U.S. cities, United States, 2008. MMWR Surveill Summ. 2011;60(14):1-34.

52.   STIGMA. Sexually Transmitted Infection testing guidelines for men who have sex with men 2010 In: Group SiGMA, editor. 2010.

53.   Guy R, Goller JL, Spelman T, El-Hayek C, Gold J, Lim M, et al. Does the frequency of HIV and STI testing among men who have sex with men in primary care adhere with Australian guidelines? Sex Transm Infect. 2010;86(5):371-6.

54.   Hussen SA, Stephenson R, del Rio C, Wilton L, Wallace J, Wheeler D, et al. HIV testing patterns among black men who have sex with men: a qualitative typology. PLoS One. 2013;8(9):e75382.

55.   Leaity S, Sherr L, Wells H, Evans A, Miller R, Johnson M, et al. Repeat HIV testing: high-risk behaviour or risk reduction strategy? AIDS. 2000;14(5):547-52.

56.   Kalichman SC, Schaper PE, Belcher L, Abush-Kirsh T, Cherry C, Williams EA, et al. It's like a regular part of gay life: repeat HIV antibody testing among gay and bisexual men. AIDS Educ Prev. 1997;9(3 Suppl):41-51.

57.   Norton J, Elford J, Sherr L, Miller R, Johnson MA. Repeat HIV testers at a London same-day testing clinic. AIDS. 1997;11(6):773-81.

58.   Fernandez MI, Perrino T, Bowen GS, Royal S, Varga L. Repeat HIV testing among Hispanic men who have sex with men--a sign of risk, prevention, or reassurance? AIDS Educ Prev. 2003;15(1 Suppl A):105-16.

59.   Vriend HJ, Stolte IG, Heijne JC, Heijman T, De Vries HJ, Geskus RB, et al. Repeated STI and HIV testing among HIV-negative men who have sex with men attending a large STI clinic in Amsterdam: a longitudinal study. Sex Transm Infect. 2014.

60.   Lee SH, Sheon N. Responsibility and risk: accounts of reasons for seeking an HIV test. Sociol Health Illn. 2008;30(2):167-81.

61.   Patel RR, Patel S, Clarke E, Khan AW, Doshi B, Radcliffe KW. Guidance and practice on frequency of HIV and sexually transmitted infection testing in men who have sex with men - what is the European situation? Int J STD AIDS. 2014;25(3):213-8.

62.   Gorbach PM, Drumright LN, Daar ES, Little SJ. Transmission behaviors of recently HIV-infected men who have sex with men. J Acquir Immune Defic Syndr. 2006;42(1):80-5.

63.   Colfax GN, Buchbinder SP, Cornelisse PG, Vittinghoff E, Mayer K, Celum C. Sexual risk behaviors and implications for secondary HIV transmission during and after HIV seroconversion. AIDS. 2002;16(11):1529-35.

64.   Fox J, White PJ, Macdonald N, Weber J, McClure M, Fidler S, et al. Reductions in HIV transmission risk behaviour following diagnosis of primary HIV infection: a cohort of high-risk men who have sex with men. HIV Med. 2009;10(7):432-8.

65.   Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011;365(6):493-505.

66.   Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 Infection with Early Antiretroviral Therapy. New England Journal of Medicine. 2011;365(6):493-505.

67.   Starting antiretroviral treatment early improves outcomes for HIV-infected individuals [press release]. 2015.

68.   Williams I, Churchill D, Anderson J, Boffito M, Bower M, Cairns G, et al. British HIV Association guidelines for the treatment of HIV-1-positive adults with antiretroviral therapy 2012. HIV Med. 2012;13 Suppl 2:1-85.

69.   Philip SS, Yu X, Donnell D, Vittinghoff E, Buchbinder S. Serosorting is associated with a decreased risk of HIV seroconversion in the EXPLORE Study Cohort. PLoS One. 2010;5(9).

70.   Vallabhaneni S, Li, X., Vittinghoff, E., Donnell, D., Pilcher, C., Buchbinder, S. , editor Seroadaptive behavior: association with seroconversion among HIV-MSM. 19th Conference on Retroviruses and Opportunisitic Infections; 2012 March 5-8 2012; Seattle.

71.   Mor Z, Davidovich, U., Bessudu-Manor, N., McFarlance, M., Feldshtein, G., Chemtob, D. High-risk behaviour in steady and in casual relationships among men who have sex with men in Israel. Sex Transm Infect. 2011;87(6):532-7.

72.   Desai M, Desai S, Sullivan AK, Mohabeer M, Mercey D, Kingston MA, et al. Audit of HIV testing frequency and behavioural interventions for men who have sex with men: policy and practice in sexual health clinics in England. Sex Transm Infect. 2013;89(5):404-8.

73.   Datta J, Hickson F, Reid D, Weatherburn P. STI testing without HIV disclosure by MSM with diagnosed HIV infection in England: cross-sectional results from an online panel survey. Sex Transm Infect. 2013;89(7):602-3.

74.   McDaid LM, Li J, Knussen C, Flowers P. Sexually transmitted infection testing and self-reported diagnoses among a community sample of men who have sex with men, in Scotland. Sex Transm Infect. 2013;89(3):223-30.

75.   Fernyak SE, Page-Shafer K, Kellogg TA, McFarland W, Katz MH. Risk behaviors and HIV incidence among repeat testers at publicly funded HIV testing sites in San Francisco. J Acquir Immune Defic Syndr. 2002;31(1):63-70.

76.   MacKellar DA, Valleroy LA, Secura GM, Bartholow BN, McFarland W, Shehan D, et al. Repeat HIV testing, risk behaviors, and HIV seroconversion among young men who have sex with men: a call to monitor and improve the practice of prevention. J Acquir Immune Defic Syndr. 2002;29(1):76-85.

77.   Harte D, Mercey D, Jarman J, Benn P. Is the recall of men who have sex with men (MSM) diagnosed as having bacterial sexually transmitted infections (STIs) for re-screening a feasible and effective strategy? Sex Transm Infect. 2011;87(7):577-82.

78.   Lorenc T, Marrero-Guillamon I, Llewellyn A, Aggleton P, Cooper C, Lehmann A, et al. HIV testing among men who have sex with men (MSM): systematic review of qualitative evidence. Health Educ Res. 2011;26(5):834-46.

79.   de Wit JB, Adam PC. To test or not to test: psychosocial barriers to HIV testing in high-income countries. HIV Med. 2008;9 Suppl 2:20-2.

80.   de Wit JB, Adam, P.C. . To test or not to test: psychosocial barriers to HIV testing in high-income countries. HIV Med. 2008;9(Suppl 2):20-2.

81.   Deblonde J, De Koker P, Hamers FF, Fontaine J, Luchters S, Temmerman M. Barriers to HIV testing in Europe: a systematic review. Eur J Public Health. 2010;20(4):422-32.

82.   Dodge B, Jeffries WLt, Sandfort TG. Beyond the Down Low: sexual risk, protection, and disclosure among at-risk Black men who have sex with both men and women (MSMW). Arch Sex Behav. 2008;37(5):683-96.

83.   Weinhardt LS, Carey MP, Johnson BT, Bickham NL. Effects of HIV counseling and testing on sexual risk behavior: a meta-analytic review of published research, 1985-1997. Am J Public Health. 1999;89(9):1397-405.

84.   Lekas HM, Schrimshaw EW, Siegel K. Pathways to HIV testing among adults aged fifty and older with HIV/AIDS. AIDS Care. 2005;17(6):674-87.

85.   Mimiaga MJ, Goldhammer H, Belanoff C, Tetu AM, Mayer KH. Men who have sex with men: perceptions about sexual risk, HIV and sexually transmitted disease testing, and provider communication. Sex Transm Dis. 2007;34(2):113-9.

86.   Spielberg F, Kurth A, Gorbach PM, Goldbaum G. Moving from apprehension to action: HIV counseling and testing preferences in three at-risk populations. AIDS Educ Prev. 2001;13(6):524-40.

87.   Flowers P, Duncan B, Knussen C. Re-appraising HIV testing: an exploration of the psychosocial costs and benefits associated with learning one's HIV status in a purposive sample of Scottish gay men. Br J Health Psychol. 2003;8(Pt 2):179-94.

88.   Morin SF, Khumalo-Sakutukwa G, Charlebois ED, Routh J, Fritz K, Lane T, et al. Removing barriers to knowing HIV status: same-day mobile HIV testing in Zimbabwe. J Acquir Immune Defic Syndr. 2006;41(2):218-24.

89.   Flowers P, Knussen C, Li J, McDaid L. Has testing been normalized? An analysis of changes in barriers to HIV testing among men who have sex with men between 2000 and 2010 in Scotland, UK. HIV Med. 2013;14(2):92-8.

90.   Godin G, Naccache, H., Pelletier, R. Seeking medical advice if HIV symptoms are suspected. Qualitative study of beliefs among HIV-negative gay men Can Fam Physician 2000;46(861-8).

91.   Flowers P, Dnucan B, Frankis J. Community, responsibility and culpability: HIV risk-mangement amongst Scottish gay men J Community Appl Soc Psychol 2000;10:285-300.

92.   Kellerman SE, Lehman JS, Lansky A, Stevens MR, Hecht FM, Bindman AB, et al. HIV testing within at-risk populations in the United States and the reasons for seeking or avoiding HIV testing. J Acquir Immune Defic Syndr. 2002;31(2):202-10.

93.   Delpierre C, Dray-Spira R, Cuzin L, Marchou B, Massip P, Lang T, et al. Correlates of late HIV diagnosis: implications for testing policy. Int J STD AIDS. 2007;18(5):312-7.

94.   Mikolajczak J, Hospers HJ, Kok G. Reasons for not taking an HIV-test among untested men who have sex with men: an Internet study. AIDS Behav. 2006;10(4):431-5.

95.   Knussen C, Flowers P, Church S. The intentions of gay men in taking an HIV test. Cult Health Sex. 2004;6(1):45-59.

96.   Flowers P, Knussen C, Duncan B. Re-appraising HIV Testing among Scottish Gay Men: The Impact of New HIV Treatments. J Health Psychol. 2001;6(6):665-78.

97.   Stolte IG, de Wit JB, Kolader ME, Fennema HS, Coutinho RA, Dukers NH. Low HIV-testing rates among younger high-risk homosexual men in Amsterdam Sex Transm Infect. 2008;83(5):287-91

98.   Forsyth SF, Agogo EA, Lau L, Jungmann E, Man S, Edwards SG, et al. Would offering rapid point-of-care testing or non-invasive methods improve uptake of HIV testing among high-risk genitourinary medicine clinic attendees? A patient perspective. Int J STD AIDS. 2008;19(8):550-2.
99.   Blas MM, Alva IE, Cabello R, Carcamo C, Kurth AE. Risk behaviors and reasons for not getting tested for HIV among men who have sex with men: an online survey in Peru. PLoS One. 2011;6(11):e27334.
100.   Mounier-Jack S, Nielsen S, Coker RJ. HIV testing strategies across European countries. HIV Med. 2008;9 Suppl 2:13-9.
101.   Institute of Medicine of the National Academies. HIV screening and access to care. Exploring barriers and facilitators to expanded HIV testing. . Washington D.C. : 2011.
102.   Stephenson R, White D, Darbes L, Hoff C, Sullivan P. HIV Testing Behaviors and Perceptions of Risk of HIV Infection Among MSM with Main Partners. AIDS Behav. 2015;19(3):553-60.
103.   Mitchell JW, Horvath KJ. Factors associated with regular HIV testing among a sample of US MSM with HIV-negative main partners. J Acquir Immune Defic Syndr. 2013;64(4):417-23.
104.   Sullivan PS, Salazar L, Buchbinder S, Sanchez TH. Estimating the proportion of HIV transmissions from main sex partners among men who have sex with men in five US cities. Aids. 2009;23(9):1153-62.
105.   Phillips G, 2nd, Magnus M, Kuo I, Shelley KD, Rawls A, West-Ojo T, et al. Correlates of frequency of HIV testing among men who have sex with men in Washington, DC. AIDS Care. 2013.
106.   Spielberg F, Critchlow C, Vittinghoff E, Coletti AS, Sheppard H, Mayer KH, et al. Home collection for frequent HIV testing: acceptability of oral fluids, dried blood spots and telephone results. HIV Early Detection Study Group. AIDS. 2000;14(12):1819-28.
107.   Phillips KA, Paul J, Kegeles S, Stall R, Hoff C, Coates TJ. Predictors of repeat HIV testing among gay and bisexual men. AIDS. 1995;9(7):769-75.
108.   Vernon KA, Mulia N, Downing M, Knight K, Riess T. "I don't know when it might pop up": understanding repeat HIV testing and perceptions of HIV among drug users. J Subst Abuse. 2001;13(1-2):215-27.
109.   Car J, Gurol-Urganci I, de Jongh T, Vodopivec-Jamsek V, Atun R. Mobile phone messaging reminders for attendance at healthcare appointments. Cochrane Database of Systematic Reviews [Internet]. 2012; (7). Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007458.pub2/abstract.
110.   Koury E, Faris C. Mobile phones and clinic appointments: the start of a beautiful new friendship? . Britush Journal of Healthcare Computing & Information Management. 2005;22(8):18-20.
111.   Guy R, Wand H, Knight V, Kenigsberg A, Read P, McNulty AM. SMS reminders improve re-screening in women and heterosexual men with chlamydia infection at Sydney Sexual Health Centre: a before-and-after study. Sex Transm Infect. 2013;89(1):11-5.
112.   Downing SG, Cashman C, McNamee H, Penney D, Russell DB, Hellard ME. Increasing chlamydia test of re-infection rates using SMS reminders and incentives. Sex Transm Infect. 2013;89(1):16-9.
113.   Woodhall S, Clarke, J., Bone, A. . Should current chlamydia testing recommendations be changed to incorporate a recommendation for repeat

testing following a positive test sooner than one year? . Public Health England 2012.

114.   Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. Am J Prev Med. 2009;36(2):165-73.

115.   Kannisto KA, Koivunen MH, Valimaki MA. Use of mobile phone text message reminders in health care services: a narrative literature review. Journal of medical Internet research. 2014;16(10):e222.

116.   Hovarth T, Azman, H., Kennedy, GE., Rutherford, GW. . Mobile phone text messaging for promoting adherence to antiretroviral therapy in patients with HIV infection. Cochrane Database of Systematic Reviews. 2012;3.

117.   Vervloet M, Linn AJ, van Weert JC, de Bakker DH, Bouvy ML, van Dijk L. The effectiveness of interventions using electronic reminders to improve adherence to chronic medication: a systematic review of the literature. Journal of the American Medical Informatics Association : JAMIA. 2012;19(5):696-704.

118.   Biosure. BioSURE HIV self test 2015 [cited 2015 8th May]. Available from: http://www.biosure.co.uk.

119.   Fisher M, Wayal S, Smith H, Llewellyn C, Alexander S, Ison C, et al. Home Sampling for Sexually Transmitted Infections and HIV in Men Who Have Sex with Men: A Prospective Observational Study. PLoS One. 2015;10(4):e0120810.

120.   Ahmed-Little Y, Bothra V, Cordwell D, Freeman Powell D, Ellis D, Klapper P, et al. Attitudes towards HIV testing via home-sampling kits ordered online (RUClear pilots 2011-12). Journal of public health (Oxford, England). 2015.

121.   Brady M. O21: Home HIV sampling linked to national HIV testing campagins: a novel approach to improve HIV diagnosis. Third Joint Conference of BHIVA with BASHH; 1-3 April; Liverpool2014.

122.   Branson BM. Home sample collection tests for HIV infection. JAMA. 1998;280(19):1699-701.

123.   Centers for Disease Control and Prevention. HIV prevention in the United States: expanding the impact 2015 [cited 2015 20th May]. Available from: http://www.cdc.gov/nchhstp/newsroom/HIVFactSheets/Challenges/TooFewPeople.htm.

124.   Skolnik HS, Phillips KA, Binson D, Dilley JW. Deciding where and how to be tested for HIV: what matters most? J Acquir Immune Defic Syndr. 2001;27(3):292-300.

125.   NHS Choices. Home HIV testing kits now legal in UK 2014 [cited 2014 28th November]. Available from: http://www.nhs.uk/news/2014/04April/Pages/Home-HIV-testing-kits-now-legal-in-UK.aspx.

126.   Spielberg F, Levine RO, Weaver M. Self-testing for HIV: a new option for HIV prevention? Lancet Infect Dis. 2004;4(10):640-6.

127.   Wright AA, Katz IT. Home testing for HIV. N Engl J Med. 2006;354(5):437-40.

128.   Frith L. HIV self-testing: a time to revise current policy. Lancet. 2007;369(9557):243-5.

129.   Pant Pai N, Balram B, Shivkumar S, Martinez-Cajas JL, Claessens C, Lambert G, et al. Head-to-head comparison of accuracy of a rapid point-of-care HIV test with oral versus whole-blood specimens: a systematic review and meta-analysis. Lancet Infect Dis. 2012;12(5):373-80.

130.   BV. ME. HIV home testing, the key to reaching high risk groups. 2008.
131.   Lee VJ, Tan SC, Earnest A, Seong PS, Tan HH, Leo YS. User acceptability and feasibility of self-testing with HIV rapid tests. J Acquir Immune Defic Syndr. 2007;45(4):449-53.
132.   Carballo-Dieguez A, Frasca T, Dolezal C, Balan I. Will gay and bisexually active men at high risk of infection use over-the-counter rapid HIV tests to screen sexual partners? J Sex Res. 2012;49(4):379-87.
133.   Katz D, Golden, MR., Hughes, JP., Farquhar, C., Stekler, JD. . Acceptability and ease of use of home self-testing for HIV among MSM Conference on Retroviruses and Opportunisitic Infections Seattle, WA 2012.
134.   Sharma A, Sullivan PS, Khosropour CM. Willingness to Take a Free Home HIV Test and Associated Factors among Internet-Using Men Who Have Sex with Men. J Int Assoc Physicians AIDS Care (Chic). 2011;10(6):357-64.
135.   Estcourt C, Saunders, J., Mercer, C., Sutcliffe, L., Hart, G. . Exploring the acceptability of medical, educational and sport settings for STI screening: stratified random probability survey of young men in the UK Sex Transm Infect. 2011;87(suppl 1):A342.
136.   Saunders JM, Mercer CH, Sutcliffe LJ, Hart GJ, Cassell J, Estcourt CS. Where do young men want to access STI screening? A stratified random probability sample survey of young men in Great Britain. Sex Transm Infect. 2012;88(6):427-32.
137.   Napierala Mavedzenge S, Baggaley R, Corbett EL. A review of self-testing for HIV: research and policy priorities in a new era of HIV prevention. Clin Infect Dis. 2013;57(1):126-38.
138.   Ajzen I. The Theory of Planned Behaviour 2006 [cited 2013 15th August]. Available from: http://people.umass.edu/aizen/tpb.diag.html.
139.   Ajzen I. Perceived Behavioural Control [cited 2013 15th August]. Available from: http://people.umass.edu/aizen/pbc.html.
140.   Ajzen I. Actual Behavioural Control [cited 2013 15th August]. Available from: http://people.umass.edu/aizen/abc.html.
141.   Fishbein M, Ajzen, I. . Belief, attitude, intention, and behaviour: an introduction to theory and research Reading, MA Addison-Wesley 1975.
142.   Sheppard BH, Hartwick, J., Warshaw, P.R. . The theory of reasoned action: a meta-analysis of past research with recommendations for modifications and future research Journal of Consumer Research 1988;15:325-43.
143.   Bandura A. Self efficacy: the exercise of self-control New York: W.H. Freeman 1997.
144.   Bandura A, Adams NE, Beyer J. Cognitive processes mediating behavioral change. J Pers Soc Psychol. 1977;35(3):125-39.
145.   Azjen I. Frequently asked questions 2011 [cited 2013 22nd August]. Available from: http://people.umass.edu/aizen/faqtxt.html.
146.   Ajzen I. Perceived behavioural control, self-efficacy, locus of control, and the theory of planned behaviour. . J Appl Soc Psychol 2002;32:665-83.
147.   Ajzen I. Constructing a TPB questionnaire: Conceptual and methodological considerations. 2002.
148.   Hausenblas H, Carron AV, Mack DE. Application of the theories of reasoned action and planned behaviour to exercise behaviour. Journal of Sport and Exercise Psychology. 1997;19:36-51.

149.   Blue C. The predictive capacity of the theory of reasoned action and the theory of planned behavior in exercise research: An integrated literature review. Research in Nursing and Health. 2007;18(2):105-21.

150.   Reinecke J, Schmidt P, Azjen I. Application of the theory of planned behavior to adolscent condom use: A panel study Journal of Applied Social Psychology. 1996;26:749-72.
151.   Blanchard CM, Courneya KS, Rodgers WM, Murnaghan DM. Determinants of exercise intention and behavior in survivors of breast and prostate cancer: an application of the theory of planned behavior. Cancer Nurs. 2002;25(2):88-95.
152.   Gardner RE, Hausenblaus, H.A. . Understanding exercise and diet motivation in overweight women enrolled in a weight loss program: A prospective study using the theory of planned behavior Journal of Applied Social Psychology. 2004;34:1353- 70.
153.   Chapman KM, Ham JO, Patricia L, Winter L. Applying behavioural models to dietary education of elderly diabetic patients Journal of Nutrition Education 1995;27:75-9.
154.   Conner M, Kirk SF, Cade JE, Barrett JH. Why do women use dietary supplements? The use of the theory of planned behaviour to explore beliefs about their use. Soc Sci Med. 2001;52(4):621-33.
155.   Conner M, Martin E, Silverdale N, Grogan S. Dieting in adolescence: An application of the theory of planned behaviour. British Journal of Health Psychology 1997;2(Part 4):315-25.
156.   Godin G, Kok G. The theory of planned behavior: a review of its applications to health-related behaviors. Am J Health Promot. 1996;11(2):87-98.
157.   Munro S, Lewin S, Swart T, Volmink J. A review of health behaviour theories: how useful are these for developing interventions to promote long-term medication adherence for TB and HIV/AIDS? BMC Public Health. 2007;7:104.
158.   Jonas K, Doll J. A critical evaluation of the theory of reasoned action and the theory of planned behaviour. Zeischrift fur Sozialpsychologie. 1996;27:18-31.
159.   Conner M, Armitage CJ. Extending the theory of planned behaviour: A review and avenues for further research J Appl Soc Psychol. 1998;28(15):1429-64.
160.   Armitage CJ, Conner M. Efficacy of the Theory of Planned Behaviour: a meta-analytic review. Br J Soc Psychol. 2001;40(Pt 4):471-99.
161.   Rosenstock IM, Strecher, V.J., Becker, M.H. . The health belief model and HIV risk behavior change. AIDS prevention and mental health. 1994:5-24.
162.   Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the Health Belief Model. Health education quarterly. 1988;15(2):175-83.
163.   Taylor D, Bury M, Campling N, Carter S, Garfied S, Newbold J, Rennie T. A review of the use of the health belief model (HBM), the theory of reasoned action (TRA), the theory of planned behaviour (TPB) and the trans-theoretical model (TTM) to study and predict health related behaviour change. National Institute for Clinical Excellence (NICE): 2006.
164.   Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. J Consult Clin Psychol. 1983;51(3):390-5.

165.   Schwarzer R. Modeling health behavior change: how to predict and modify the adoption and maintenance of health behaviors. Applied Psychology. 2008;57(1):1-29.

166.   Hardeman W, Johnston M, Johnston D, Bonetti D, Wareham N, Kinmouth A. Application of the theory of planned behaviour in behaviour change interventions Psychology and Health 2002;17(2).

167.   Guy R, Hocking J, Low N, Ali H, Bauer HM, Walker J, Klausner JD, Donovan B, Kaldor JM. Interventions to increase rescreening for repeat chlamydial infections Sexually Transmitted Diseases. 2012 39(2):136-46.

168.   Bourne C, Knight V, Guy R, Wand H, Lu H, McNulty A. Short message service reminder intervention doubles sexually transmitted infection/HIV re-testing rates among men who have sex with men. Sex Transm Infect. 2011;87(3):229-31.

169.   Harte D, Jarman J, Mercey D, Copas A, Benn P. Recall of men who have sex with men diagnosed with bacterial sexually transmitted infections for retesting: A feasible and effective strategy? HIV Medicine. 2010;11:17-8.

170.   Gift TL, Malotte K, Ledsky R, Hogben M, Middlestadt S, Vandevanter NL, St Lawrence JS, and the GCAP Study Group A cost-effectiveness analysis of interventions to increase repeat testing in patients treated for gonorrhea or chlamydia at public sexually transmitted disease clinics Sexually Transmitted Diseases. 2005;32(9):542-49

171.   Malotte CK, Ledsky R, Hogben M, Larro M, Middlestadt S, St Lawrence JS, et al. Comparison of methods to increase repeat testing in persons treated for gonorrhea and/or chlamydia at public sexually transmitted disease clinics. Sexually Transmitted Diseases. 2004;31(11):637-42.

172.   Gotz HM, van den Broek IVF, Hoebe CJPA, Brouwers EEHG, Pars LL, Fennema JSA, Koekenbier RH, van Ravesteijn S, Op de Coul ELM, van Bergen J. High yield of reinfections by home-based automatic rescreening of chlamydia positives in a large-scale register-based screening programme and determinants of repeat infections Sexually Transmitted Infections. 2013 89:63-9.

173.   Ajzen I, Fishbein M. Attitude-behavior relations: A theoretical analysis and review of empirical research Psychol Bull. 1977;84:888-918.

174.   Blanchard JF, Aral SO. Program Science: an initiative to improve the planning, implementation and evaluation of HIV/sexually transmitted infection prevention programmes. Sex Transm Infect. 2011;87(1):2-3.

175.   Parkhurst J, Weller I, Kemp J. Getting research into policy, or out of practice, in HIV? Lancet. 2010;375(9724):1414-5.

176.   Bonell CP, Hargreaves J, Cousens S, Ross D, Hayes R, Petticrew M, et al. Alternatives to randomisation in the evaluation of public health interventions: design challenges and solutions. J Epidemiol Community Health. 2011;65(7):582-7.

177.   Bourne C, Zablotska I, Williamson A, Calmette Y, Guy R. Promotion and uptake of a new online partner notification and retesting reminder service for gay men. Sex Health. 2012;9(4):360-7.

178.   Jabine T, Straf, ML., Tanur, JM., Tourangeau, R. . Cognitive aspects of survey methodology: building a bridge between disciplines Washington D.C. : National Academy Press,. 1984.

179.   Tourangeau R. Cognitive sciences and survey methods. In: Jabine T, Straf ML, Tanur JM, Tourangeau R, editor. Cognitive aspects of survey methodolgy:

building a bridge between disciplines Washington D.C. : National Academy Press 1984. p. 73-100.

180.   Tourangeau R, Rips LJ, Rasinski K The psycology of survey responses Cambridge: Cambridge University Press; 2000.

181.   Blair E, Burton S. Cognitive processes used by survey respondents in answering behavioural frequency questions. J Consumer Research. 1987;14(280-288).

182.   DeMaio T, Landreth A . Do different cognitive interview techniques produce different results? In: Presser S, Rothgeb JM, Couper MP, Lessler JT, Martin E, Martin J, Singer E, editor. Methods for testing and evaluating survey questions Hoboken, NJ: Wiley; 2004.

183.   Willis G, DeMaio T, Harris-Kojetin B. Is the bandwagon headed to the methodological promised land? Evaluating the validity of cognitive interviewing techniques In: Sirken M, Herrmann D, Schechter S, Schwarz N, Tanur J, Tourangeau R, editor. Cognition and Survey Research New York: Wiley 1999.

184.   Ericsson K, Simon HA. Protocol analysis: verbal reports as data Cambridge, MA MIT Press; 1984.

185.   Forsyth B, Lessler JT. Cognitive laboratory methods: a taxonomy In: al. Be, editor. Measurement errors in surveys. New York Wiley; 1991.

186.   Willis G. Cognitive interviewing: A tool for improving interview design. Thousand Oaks, CA: Sage; 2005.

187.   Willis G. Cognitive interviewing revisited: A useful technique, in theory? In: Presser S, Couper, MP., Lessler, JT., Martin, E., Martin, J., Rothgeb, JM., Singer E., editor. Methods for testing and evaluating survey questionnaires. Hoboken, NJ: Wiley; 2004.

188.   Belson WA. The design and understanding of survey questions: Gower; 1981.

189.   Campanelli P, Martin EA, Rothgeb JM. The use of respndent and interviewer debriefing studies as a way to study response error in survey data. The Statistician. 1991;40(253-64).

190.   Willis G, Schechter S. Evaluation of cognitive interviewing techniques: do the results generalise to the field? Bulletin de Methodologie Sociologique. 1997;55:40-66.

191.   Dillman D, Redline C. Testing paper self-administered questionnaires: cognitive interview and field test comparisons. In: al. Pe, editor. Methods for testing and evaluating survey questions Hoboken, NJ. : Wiley; 2004.

192.   Forsyth B, Rothgeb J, Willis G. Does question pretesting make a difference? An empirical test. In: al. Pe, editor. Testing and evaluating survey questionnaires. Hoboken, NJ. : Wiley; 2004.

193.   Knafl K, Deatrick J, Gallo A, Holcombe G, Bakitas M, Dixon J, et al. The analysis and interpretation of cognitive interviews for instrument development. Res Nurs Health. 2007;30(2):224-34.

194.   Presser S, Couper MP, Lessler JT, Martin E, Martin J, Rothgeb JM, Singer E. Methods for testing and evaluating survey questionnaires. Hoboken, NJ. : Wiley; 2004.

195.   Beatty P, Willis GB. Research systhesis: the practice of cognitive interviewing. Public Opinion Quarterly. 2007;71(2):287-311.

196.   Willis G, Schechter S, Whitaker K. A comparison of cognitive interviewing, expert interview, and behavior coding: what do they tell us? Proceedings of the

American Statistical Association (Survey Research Methods Section). 1999:28-37.

197.   Willis G. Cognitive interviewing and questionnaire design: a training manual In: Office of Research Methodology NCfHS, editor. Washington DC. 1994.

198.   DeMaio T, Rothgeb JM. Cognitive interviewing techniques in the lab and in the field In: Sudman Sa, editor. Answering Questions: Methodology for Dtermining Cognitive and Communicative Processes in Survey Research. San Francisco Jossey-Bass; 1996.

199.   Esposisto J, Campanelli PC, Rothgeb J, Polivka AE. Determining which questions are best: methodologies for evaluating survey questions. Proceedings of the American Statistical Association (Survey Research Methods Section). 1991:46-55.

200.   Lessler J, Forsyth BH. A coding system for appraising questionnaires. In: Schwartz N, Sudman, S. , editor. Answering questions: Methodology for determining cognitive and communicative processes in survey research. San Francisco: Jossey-Bass; 1996.

201.   Presser J, Blair J. Survey pretesting: Do different methods produce different results? Sociological Methodology 1994;24:73-104.

202.   Drennan J. Cognitive interviewing: verbal data in the design and pretesting of questionnaires. J Adv Nurs. 2003;42(1):57-63.

203.   Blair J, Brick, P.D. , editor Methods for the analysis of cognitive interviews. Section on Survey Research Methods- Joint Statistical Meeting 2010; 2010.

204.   Willis G. Cognitive interviewing: A how to guide. Reducing survey error through research on the cognitive and decision processes in surveys. . In: Caspar RA, Lessler, J.T., Willis, G.B. , editor. 1999 Meeting of the American Statistical Association: Research Triangle Institute,. 1999.

205.   Conrad F, Blair J . From impressions to data: increasing the objectivity of cognitive interviews. Proc Section on Survey Research Methods American Statistical Association. 1996:1-9.

206.   Rothgeb J, Willis G, Forsyth, B. Questionnaire pre-testing methods: Do different techniques and different organisations produce similar results? Proc Section on Survey Research Methods American Statistical Association. 2001.

207.   Ritchie J, Lewis J., McNaughton Nichols, C., Ormston, R. . Qualitative Research Practice. 2nd Edition ed. London: Sage; 2013.

208.   Fowler F. Survey Research Methods. Bickman L, Rog, D. , editor. Thousand Oaks, CA: Sage; 2009.

209.   DeVellis R. Scale development: Theory and applications. Thousand Oaks, CA: Sage; 2003.

210.   Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometria. 1951;16:297-334.

211.   Santos J. Cronbach's alpha: a tool for assessing the reliability of scales. Journal of Extension. 1999;37(2):2TOT3.

212.   Sijtsma K. On the Use, the Misuse, and the Very Limited Usefulness of Cronbach's Alpha. Psychometrika. 2009;74(1):107-20.

213.   Catania J, Gibson DR, Chitwood DD, Coates TJ. Methodological problems in AIDS behavioral research: influences on measurement error and participation bias in studies of sexual behavior. Psychol Bull. 1990;108(3):339-62.

214.   Blake S, Saharp SS, Temoshok L. Methodological considerations in developing measures of HIV risk-relevant behaviours and attitudes; an empirical illustration Psychol and Health. 1992;6:265-80.
215.   The Kinsey Institute. Data from Alfred Kinsey's studies 1996-2003 [cited 2013 13th December]. Available from: http://www.kinseyinstitute.org/research/ak-data.html.
216.   Fenton KA, Johnson AM, McManus S, Erens B. Measuring sexual behaviour: methodological challenges in survey research. Sex Transm Infect. 2001;77(2):84-92.
217.   Wellings K, Cleland J. Surveys on sexual health: recent developments and future directions. Sex Transm Infect. 2001;77(4):238-41.
218.   Catania J, Binson, D., Van der Straten, A., Stone, V.   . Methodological research on sexual behaviour in the AIDS era. Annual Review of Sex Research. 1995;6(1):77-125.
219.   Natsal. The National Survey of Sexual Attitudes and Lifestyles 2013 [cited 2013 December 10th]. Available from: http://www.natsal.ac.uk.
220.   Erens B, Phelps A, Clifton S, Hussey D, Mercer CH, Tanton C, Sonnenberg P, Macdowall W, Copas AJ, Field N, Mitchell K, Datta J, Hawkins V, Ison C, Beddows S, Soldan K, Coelho da Silva F, Alexander S, Wellings K, Johnson AM. National Survey of Sexual Attitudes and Lifestyles 3: Technical Report. Volume 1: Methodology London: 2013.
221.   Nardone A, Dodds JP, Mercey DE, Johnson AM. Active surveillance of sexual behaviour among homosexual men in London. Commun Dis Public Health. 1998;1(3):197-201.
222.   Dodds JP, Mercey DE, Parry JV, Johnson AM. Increasing risk behaviour and high levels of undiagnosed HIV infection in a community sample of homosexual men. Sex Transm Infect. 2004;80(3):236-40.
223.   Elkstrand M, Coates TJ, . Maintenance of safe sexual behaviours and predictors of risky sex: the San Francisco Men's Health Study. Am J Public Health. 1990;80:973-7.
224.   Nardone A, Mercey DE, Johnson AM. Surveillance of sexual behaviour among homosexual men in a central London health authority. Genitourin Med. 1997;73(3):198-202.
225.   Hope VD, MacArthur C. Safer sex and social class: findings from a study of men using the 'gay scene' in the West Midlands region of the United Kingdom. AIDS Care. 1998;10(1):81-8.
226.   Day S, Ward H, Ghani A, Bell G, Goan U, Parker M, et al. Sexual histories, partnerships and networks associated with the transmission of gonorrhoea. Int J STD AIDS. 1998;9(11):666-71.
227.   de Vincenzi I. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. European Study Group on Heterosexual Transmission of HIV. N Engl J Med. 1994;331(6):341-6.
228.   Ghani AC, Ison CA, Ward H, Garnett GP, Bell G, Kinghorn GR, et al. Sexual partner networks in the transmission of sexually transmitted diseases. An analysis of gonorrhea cases in Sheffield, UK. Sex Transm Dis. 1996;23(6):498-503.
229.   Ghani AC, Swinton J, Garnett GP. The role of sexual partnership networks in the epidemiology of gonorrhea. Sex Transm Dis. 1997;24(1):45-56.

230.   Parker R, Carballo M. Qualitative research on homosexual and bisexual behavior relevant to HIV/AIDS. J Sex Res. 1990;27:497-525.
231.   van der Elst E, Mbogua J, Operario D, Mutua G, Kuao C, Mugo P, Kanungi J, Singh S, Haberer J, Priddy F, Sanders EJ. High accepability of HIV pre-exposure prophylaxis but challenges in adherence and use: qualitative insights from a phase I trial of intermittent and daily PrEP in at-risk populations in Kenya. AIDS and Behaviour. 2013;17(6):2162-72.
232.   Strassberg DS, Lowe K. Volunteer bias in sexuality research. Arch Sex Behav. 1995;24(4):369-82.
233.   Dunne MP, Martin NG, Bailey JM, Heath AC, Bucholz KK, Madden PA, et al. Participation bias in a sexuality survey: psychological and behavioural characteristics of responders and non-responders. Int J Epidemiol. 1997;26(4):844-54.
234.   Copas AJ, Johnson AM, Wadsworth J. Assessing participation bias in a sexual behaviour survey: implications for measuring HIV risk. AIDS. 1997;11(6):783-90.
235.   Wiederman MW. Volunteer bias in sexuality research using college student participants. The Journal of Sex Research. 1999;36(1):59-66.
236.   Johnson AM, Wadsworth, J., Wellings, K., Bradshaw, S. . Sexual behaviour in Britain: The National Survey of Sexual Attitudes and Lifestyles. London: Penguin Books Ltd; 1994.
237.   Mercer CA. Measuring sexual behaviour and risk 2010 [cited 2013 19th December]. Available from:
ukdataservice.ac.uk/media/262883/discover_sqb_sex_mercer.pdf

238.   Catania J, Gibson, DR., Marin B., Coates, TJ., Greenblatt, RM. . Response bias in assessing sexual behaviours relevant to HIV transmission Evaluation and Program Planning. 1990;13(1):19-29.
239.   Blaikie N. Approaches to social inquiry. 2nd edition ed. Polity, editor: Cambridge; 2007.
240.   Flick U, Hochshule AS. How many qualitative inteviews is enough? National Centre for Research Methods Review Paper, 2012.
241.   Kvale S, Brinkman S. Interviews- Learning the craft of qualitative research interviewing. London: Sage; 2009.
242.   Moran-Ellis VDA, Cronin A, Dickinson M, Fielding J, Sleney J, Thomas H. Traingulation and integration: processes, claims and implications. Qualitative Research. 2006;6(1):45-59.
243.   Bryman A. Integrating quantitative and qualitative research: how is it done? Qualitative Research. 1006;6(1):97-113.
244.   Greene JC, Caracelli VJ, Graham WF. Toward a conceptual framework for mixed-method evaluation designs. Educational evaluation and policy analysis. 1989;11(3):255-74.
245.   Mason J. Working paper: six stractegies for mixing mehods and linking data in social science research. In: Methods ENCfR, editor. 2006.
246.   Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med. 2009;6(7):e1000097.
247.   Atun R, Sittampalam S. A review of the characteristics and benefits of SMS delivering in healthcare. Vodaphone Group Plc. 2006.

248.   Kaplan W. Can the ubiquitous power of mobile phones be used to improve health outcomes in developing countries? Global Health 2006;23(2):9.

249.   Read TR, Hocking JS, Bradshaw CS, Morrow A, Grulich AE, Fairley CK, et al. Provision of rapid HIV tests within a health service and frequency of HIV testing among men who have sex with men: randomised controlled trial. BMJ. 2013;347:f5086.

250.   Wayal S, Llewellyn C, Smith H, Fisher M. Home sampling kits for sexually transmitted infections: preferences and concerns of men who have sex with men. Cult Health Sex. 2011;13(3):343-53.

251.   National Institute for Health and Clinical Excellence. Clinical guideline development methods: The guidelines manual 2012. In: National Institute for Health and Clinical Excellence, editor. 2012.

252.   National Institute for Health and Clinical Excellence. Methods for the development of NICE public health guidance (second edition) In: National Institute for Health and Clinical Excellence, editor. London2009

253.   Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S, et al. Grading quality of evidence and strength of recommendations. BMJ. 2004;328(7454):1490.

254.   Siersma V, Als-Nielsen B, Chen W, Hilden J, Gluud LL, Gluud C. Multivariable modelling for meta-epidemiological assessment of the association between trial quality and treatment effects estimated in randomized clinical trials. Stat Med. 2007;26(14):2745-58.

255.   Deeks JJ DJ, D'Amico R, Snowden AJ, Sakarovitch C, Song F, Petticrew M, Altman DJ. Evaluating non-randomised intervention studies. Health Technology Assessment. 2003;7(27):1-179.

256.   StataCorp. Stata Statistical Software: Release 10. College Station, TX: StataCorp LP; 2007.

257.   Sterne J, Bradburn MJ, Egger M. Chapter 18: Meta-analysis in Stata. In: Egger M, Davey Smith G, Altman DG, editor. Systematic Reviews. London. : BMJ Publishing Group,. ; 2001.

258.   Harbord RM, Egger M, Sterne JA. A modified test for small-study effects in meta-analyses of controlled trials with binary endpoints. Stat Med. 2006;25(20):3443-57.

259.   Gotz HM, Wolfers MEG, Luijendijk A, van den Broek IVF. Retesting for genital Chlamydia trachomatis among visitors of a sexually transmitted infections clinic: Randomized intervention trial of home- versus clinic-based recall. BMC Infectious Diseases. 2013;13(1).

260.   Burton J, Brook G, McSorley J, Murphy S. The utility of short message service (SMS) texts to remind patients at higher risk of STIs and HIV to reattend for testing: a controlled before and after study. Sex Transm Infect. 2013.

261.   LaMontagne DS, Baster K, Emmett L, Nichols T, Randall S, McLean L, et al. Incidence and reinfection rates of genital chlamydial infection among women aged 16-24 years attending general practice, family planning and genitourinary medicine clinics in England: A prospective cohort study by the Chlamydia Recall Study Advisory Group. Sexually Transmitted Infections. 2007;83(4):292-303.

262.   Cameron ST, Glasier A, Scott G, Young H, Melvin L, Johnstone A, et al. Novel interventions to reduce re-infection in women with chlamydia: a randomized controlled trial. Hum Reprod. 2009;24(4):888-95.

263.	Downing SG, Cashman C, McNamee H, Penney D, Russell DB, Hellard ME. Increasing chlamydia test of re-infection rates using SMS reminders and incentives. Sexually Transmitted Infections. 2013;89(1):16-9.

264.	Bourne C, Knight V, Guy R, Wand H, Lu H, McNulty A. Short message service reminder intervention doubles sexually transmitted infection/HIV re-testing rates among men who have sex with men. Sexually Transmitted Infections. 2011;87(3):229-31.

265.	Zou H, Fairley CK, Guy R, Bilardi J, Bradshaw CS, Garland SM, et al. Automated, Computer Generated Reminders and Increased Detection of Gonorrhoea, Chlamydia and Syphilis in Men Who Have Sex with Men. PLoS ONE. 2013;8(4).

266.	Guy R, Wand H, Knight V, Kenigsberg A, Read P, McNulty AM. SMS reminders improve re-screening in women and heterosexual men with chlamydia infection at sydney sexual health centre: A before-and-after study. Sexually Transmitted Infections. 2013;89(1):11-5.

267.	Walker J, Tabrizi SN, Fairley CK, Chen MY, Bradshaw CS, Twin J, et al. Chlamydia trachomatis incidence and re-infection among young women--behavioural and microbiological characteristics. PLoS ONE [Electronic Resource]. 2012;7(5):e37778.

268.	Sparks R, Helmers JRL, Handsfield HH, Totten PA, Holmes KK, Wroblewski JKH, et al. Rescreening for Gonorrhea and Chlamydial Infection through the Mail: A Randomized Trial. Sexually Transmitted Diseases. 2004;31(2):113-6.

269.	Xu F, Stoner BP, Taylor SN, Mena L, Tian LH, Papp J, et al. Use of home-obtained vaginal swabs to facilitate rescreening for Chlamydia trachomatis infections: Two randomized controlled trials. Obstetrics and Gynecology. 2011;118(2 PART 1):231-9.

270.	Cook RL, Ostergaard L, Hillier SL, Murray PJ, Chang C-CH, Comer DM, et al. Home screening for sexually transmitted diseases in high-risk young women: randomised controlled trial. Sexually Transmitted Infections. 2007;83(4):286-91.

271.	Paneth-Pollak R, Klingler EJ, Blank S, Schillinger JA. The elephant never forgets; piloting a chlamydia and gonorrhea retesting reminder postcard in an STD clinic setting. Sex Transm Dis. 2010;37(6):365-8.

272.	Bloomfield PJ, Steiner KC, Kent CK, Klausner JD. Repeat chlamydia screening by mail, San Francisco. Sexually Transmitted Infections. 2003;79(1):28-30.

273.	van den Broek IV, van Bergen JE, Brouwers EE, Fennema JS, Gotz HM, Hoebe CJ, et al. Effectiveness of yearly, register based screening for chlamydia in the Netherlands: controlled trial with randomised stepped wedge implementation. Bmj. 2012;345:e4316.

274.	Head KJ, Noar SM, Iannarino NT, Grant Harrington N. Efficacy of text messaging-based interventions for health promotion: a meta-analysis. Soc Sci Med. 2013;97:41-8.

275.	Neal R, Hussain-Gambles M, Allgar VL, Lawlor DA, Dempsey O. Reasons for and consequences of missed appointments in general practice in the UK: questionnaire survey and prospective review of medical records. . BMC Family Practice. 2005;6:47.

276.   Murdock A, Rodgers C, Lindsay H, Tham TC. Why do patients not keep their appointments? Prospective study in a gastroenterology outpatient clinic. . J R Soc Med. 2002;95(6):284-6.

277.   Balaji AB, Bowles KE, Le BC, Paz-Bailey G, Oster AM. High HIV incidence and prevalence and associated factors among young MSM, 2008. AIDS. 2013;27(2):269-78.

278.   Blas MM, Menacho LA, Alva IE, Cabello R, Orellana ER. Motivating men who have sex with men to get tested for HIV through the internet and mobile phones: a qualitative study. PLoS ONE [Electronic Resource]. 2013;8(1):e54012.

279.   Gift TL, Malotte CK, Ledsky R, Hogben M, Middlestadt S, VanDevanter NL, et al. A cost-effectiveness analysis of interventions to increase repeat testing in patients treated for gonorrhea or chlamydia at public sexually transmitted disease clinics. Sexually Transmitted Diseases. 2005;32(9):542-9.

280.   Landry H, Nur M, Jarman J. MMC/AC 3 month recall: an audit presentation 2012.

281.   NHS Institute for Innovation and Improvement. Plan, Do, Study, Act (PDSA) London: NHS Institute for Innovation and Improvement,. 2008 [cited 2013 12th December]. Available from: http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_an d_service_improvement_tools/plan_do_study_act.html.

282.   Health Research Authority. Defining Research 2009 [cited 2015 6th January]. Available from: http://www.hra.nhs.uk/documents/2013/09/defining-research.pdf.

283.   Fillingham S. What would lean healthcare look like? In: Fillingham D, editor. Lean Healthcare: Improving the patient's experience. Chichester: Kingsham Press, ; 2008. p. 35-49.

284.   Habicht JP, Victora CG, Vaughan JP. Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. Int J Epidemiol. 1999;28(1):10-8.

285.   Genitourinary medicine clinic activity dataset (GUMCADv2) [Internet]. 2013. Available from: https://http://www.gov.uk/genitourinary-medicine-clinic-activity-dataset-gumcadv2.

286.   Genitourinary Medicine Clinic Activity Dataset (GUMCAD). Demographic and STI data for HIV negative MSM attending PROUD clinics: Data sourced from the Genitourinary Medicines Clinic Activity Dataset (GUMCAD) v 2 submitted to Public Health England (PHE) 2013. 2014.

287.   Office for National Statistics. Labour Market Statistics, May 2013. 2013.

288.   Mercer CA, Prah P, Tanton C, Nardone A, Clifton S, Sonnenberg P, Johnson A. How has sexual risk behavioural and perception changed among MSM in Britain since 2000. Public Health England Conference 2014; 16-17th September 2014; Warwick ,UK2014.

289.   Census. LC5107EW: Highest level of qualification by sex. In: Statistics OLM, editor. 2011.

290.   Prost A, Chopin M, McOwan A, Elam G, Dodds J, Macdonald N, et al. "There is such a thing as asking for trouble": taking rapid HIV testing to gay venues is fraught with challenges. Sex Transm Infect. 2007;83(3):185-8.

291.   Gilbart VL, Town K, Lowndes CM. A survey of the use of text messaging for communication with partners in the process of provider-led partner notification. Sex Transm Infect. 2014.

292.   Apoola A, Radcliffe KW, Das S, Robshaw V, Gilleran G, Kumari BS, et al. Patient preferences for partner notification. Sex Transm Infect. 2006;82(4):327-9.
293.   Godin G, Conner M, Sheeran P. Bridging the intention-behaviour 'gap': the role of moral norm. Br J Soc Psychol. 2005;44(Pt 4):497-512.
294.   Sheeran P, Abraham C. Mediator of moderators: temporal stability of intention and the intention-behavior relation. Personality & social psychology bulletin. 2003;29(2):205-15.
295.   Burke B, Arkowitz, H., Menchola, M. . The efficacy of motivational interviewing: a meta-analysis of controlled clinical trials Journal of Consulting and Clinical Psychology 2003;71(5):843-61.
296.   Siegler AJ, Sullivan PS, de Voux A, Phaswana-Mafuya N, Bekker LG, Baral SD, et al. Exploring repeat HIV testing among men who have sex with men in Cape Town and Port Elizabeth, South Africa. AIDS Care. 2014:1-6.
297.   Wayal S, Llewellyn C, Smith H, Hankins M, Phillips A, Richardson D, et al. Self-sampling for oropharyngeal and rectal specimens to screen for sexually transmitted infections: acceptability among men who have sex with men. Sex Transm Infect. 2009;85(1):60-4.
298.   Greacen T, Friboulet D, Blachier A, Fugon L, Hefez S, Lorente N, et al. Internet-using men who have sex with men would be interested in accessing authorised HIV self-tests available for purchase online. AIDS Care. 2013;25(1):49-54.
299.   Rapid Response Service. Gay men's attitudes and perceptions regarding rapid HIV home testing. Toronto, ON: 2013 June 2013. Report No.
300.   McCormack S, Dunn DT, Desai M, Dolling DI, Gafos M, Gilson R, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet. 2015.
301.   Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection. New England Journal of Medicine. 2015;373(9):795-807.
302.   Bourne A RD, Hickson F, Rueda ST, Weatherburn P. The Chemsex Study: drug use in sexual settings among gay and bisexual men in Lambeth, Southwark and Lewisham London School of Hygiene & Tropical Medicine, 2014.
303.   de Tolly K, Skinner D, Nembaware V, Benjamin P. Investigation into the use of short message services to expand uptake of human immunodeficiency virus testing, and whether content and dosage have impact. Telemedicine journal and e-health : the official journal of the American Telemedicine Association. 2012;18(1):18-23.
304.   da Costa TM, Salomao PL, Martha AS, Pisa IT, Sigulem D. The impact of short message service text messages sent as appointment reminders to patients' cell phones at outpatient clinics in Sao Paulo, Brazil. International journal of medical informatics. 2010;79(1):65-70.
305.   Branson CE, Clemmey P, Mukherjee P. Text message reminders to improve outpatient therapy attendance among adolescents: a pilot study. Psychological services. 2013;10(3):298-303.
306.   Naughton F, Jamison J, Sutton S. Attitudes towards SMS text message smoking cessation support: a qualitative study of pregnant smokers. Health Educ Res. 2013;28(5):911-22.

307.   Fry JP, Neff RA. Periodic prompts and reminders in health promotion and health behavior interventions: systematic review. Journal of medical Internet research. 2009;11(2):e16.

308.   Bull F, Holt, C., Kreuter, M., Clark, E., Scharff, D. . Understanding the effects of printed health education materials: which features lead to which outcomes. J Health Communi. 2001;6:265-79.

309.   Trevena L, Davey H, Barratt A, Butow P, Caldwell P. A systematic review on communicating iwth patients about evidence. J Eval Ciln Pract. 2006;12:13-23.

310.   Andrews L, Cacho-Elizondo S, Drennan J, Tossan V. Consumer acceptance of an SMS-assisted smoking cessation intervention: a multicountry study. Health marketing quarterly. 2013;30(1):47-62.

311.   Ranjbarian B, Gharibpoor, M., Lari, A. . Attitude toward SMS advertising and derived behavioural intension, an empirical study using TPB (SEM method). Journal American Science. 2012;8(7).

312.   Campbell JL, Quincy C, Osserman J, Pederson OK. Coding in-depth semistructured interviews: problems of unitization and intercoder reliability and agreement. Sociological Methods & Research. 2013;43(3):294-320.

313.   Kelly JA, Murphy DA, Sikkema KJ, McAuliffe TL, Roffman RA, Solomon LJ, et al. Randomised, controlled, community-level HIV-prevention intervention for sexual-risk behaviour among homosexual men in US cities. Community HIV Prevention Research Collaborative. Lancet. 1997;350(9090):1500-5.

314.   Bailey J, Mann S, Wayal S, Abraham C, Murray E. Digital media interventions for sexual health promotion-opportunities and challenges. BMJ. 2015;350:h1099.

315.   Konnerup M, Kongsted HC. There is more to seeing than meets the eye: observational studies, research sythesis, and the social sciences. 2009.

316.   Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med. 2000;342(25):1887-92.

317.   ASTRA. Antiretrovirals, sexual transmission risk and attitudes 2014 [cited 2014 1st January]. Available from: http://www.astra-study.org.

318.   EMIS. European man-for-man internet sex survey 2014 [cited 2014 1st January]. Available from: http://www.sigmaresearch.org.uk/go.php?/projects/gay/project46.

319.   Office for National Statistics. Ethnic Group [cited 2014 1st January]. Available from: http://www.ons.gov.uk/ons/guide-method/measuring-equality/equality/ethnic-nat-identity-religion/ethnic-group/index.html.