Public Health England

UCL Imperial College London

Positive Voices
the national survey of people living with HIV

PHASE 3 PROTOCOL

Positive Voices: the National Survey of People Living with HIV

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A. Protocol Synopsis

Positive Voices: the national survey of people with HIV

Location	HIV clinics in England, Wales, and Northern Ireland
Period of study	Jan 2016 – Dec 2017 (24 months)(12 months preparation/groundwork, 6 months data collection, 6 months analysis)
Funding	Gilead Sciences Inc.
Ethics review	London – Harrow Research Ethics Committee (13/LO/0279)
Design	Repeat cross-sectional survey
Sample size	3,048 responses, 11,967 invitations
Population	HIV positive men and women, 18 years or older accessing HIV care

B. Background

The numbers of people living with HIV who are well and on antiretroviral therapy is increasing and represent a substantial burden on NHS resources. There was a five-fold increase in the numbers accessing care between 1997 and 2006 (HPA, 2011). Over the past 30 years, HIV disease has evolved rapidly from a condition with a poor short term prognosis to a chronic, long term condition which is associated with other chronic conditions, including hypertension, cardiovascular disease, diabetes, osteoporosis, mental and neurocognitive disorders (Friis-Moller 2008, Thiebaut 2005, De Wit 2008, Worm 2009). At the same time there is a growing body of evidence suggesting that HIV prevention interventions targeting people living with HIV, positive prevention, should be an important aspect of overall prevention strategy. Therefore, in order to plan treatment and prevention services there is an urgent need to better quantify population prevalence of chronic disease co-morbidity among people living with HIV (PLHIV), and establish population risk factors that may increase susceptibility to co-morbidities, co-infections and sexual risk.

Furthermore, although routine HIV care continues to be delivered by HIV specialist services, PLHIV are reported to consult their general practitioner four to five times a year (Evans 2009). As the population of people diagnosed with HIV live longer and their healthcare needs change, there is a need to reconsider the role of primary and social care in the management of HIV-infection, and the met and unmet healthcare needs of HIV-positive persons to ensure appropriate provision of services.

Historically, our understanding of the healthcare needs and risk behaviours of PLHIV has come from clinic- or community-based surveys conducted by academic institutions or sexual health charities (Working with HIV, Project Nasah, What do you need?, Relative Safety, SONHIA, UKCHIC). These surveys have provided valuable information which allow insights into the HIV epidemic. However, these surveys have important limitations. Firstly, surveys of PLHIV are ad hoc or occur at irregular intervals often spaced several years apart and with changing methodologies. While these studies can provide useful cross-sectional information, longitudinal or repeated cross-sectional studies using a consistent methodology and sampling frame are needed to interpret trends over time. Secondly, community-based research relies on convenience sampling and opportunistic recruitment, for example through the internet or patient groups, introduces sampling bias by excluding PLHIV who do not access such technologies or services. Similarly, surveys in clinical settings also face selection biases as well as administrative and logistical barriers. Most studies have tended to focus on large clinics in urban areas, such as London, Manchester, and Brighton. However, evidence from Public Health England shows an

increasing geographic spread of HIV cases with less than half (42%) residing in London in 2008, a decrease from 65% in 2000, a trend that is likely to continue (HPA 2012). There is also evidence of health inequalities and different needs of PLHIV who attend large HIV clinics compared to PLHIV attending medium-sized or smaller clinics (Shickle 2011). As a result, the data from these surveys have limited generalisability to the wider community of people living with HIV.

There are limited nationally representative surveys of PLHIV. The United States has invested heavily in the development of a system for collecting information on diagnosed HIV positive individuals, known as the Medical Monitoring Project (MMP). MMP involves extracting information from medical records in addition to completion of a questionnaire by PLHIV. A vast amount of resources (over US$60 million over the past five years) has been invested in achieving a representative sample of PLHIV in the context of a privatised healthcare system. In contrast, in the UK, we have the benefit of being able to access, at relatively low cost, a representative sample of PLHIV through a national register comprising nearly all individuals diagnosed with HIV infection and accessing care. This protocol describes the development, piloting and implementation of a national survey of a representative sample of PLHIV.

C. Purpose and Objectives

The number of people living with HIV in the UK is estimated at over 100,000, and is increasing annually as a result of on-going transmission and effective HIV treatment. HIV is a now a chronic disease associated with other chronic diseases, such as hyperlipidaemia, hypertension, diabetes, osteoporosis, and depression. In order to plan healthcare and prevention services, there is a need to better understand the patterns of sexual and lifestyle risk behaviour in PLHIV and how this may change over time. There is also a need to map patterns of HIV-associated chronic diseases and risk behaviours, attitudes and satisfaction with current models of care, to ensure equitable and efficient access to quality health services.

The project will utilise the existing national census of HIV positive individuals in care [SOPHID] as a national sampling frame for collecting longitudinal data on social, behavioural, and healthcare needs of HIV positive persons. SOPHID is a national public health surveillance dataset which collects anonymised demographic, clinical, and treatment data for over 85,000 PLHIV receiving care in the UK. A representative random sample of PLHIV attending HIV clinics will be invited to complete a questionnaire. Topics covered by the questionnaire include: sexual and drug taking behaviours; co-

morbidities and risk behaviours associated with chronic disease; current use of health services; quality of life; satisfaction with care (and attitudes to future possible models of care); and attitudes to, and experiences of, living with HIV.

This is a multi-site cross-sectional study in adults living with HIV who are receiving care in the UK. The principal objectives of the survey are to determine:

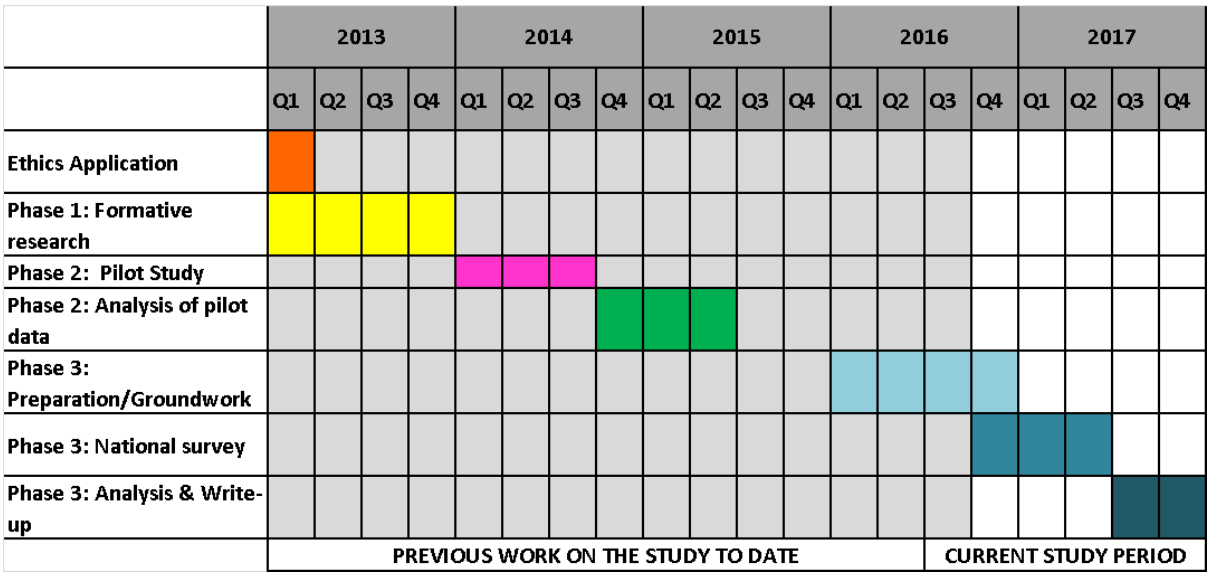
1. What are the prevalence and key determinants of sexual and other health-related risk behaviours among people living with HIV in the UK?
2. What are the self-reported prevalences of associated chronic diseases (cardiovascular disease, metabolic conditions, mental/neurocognitive disorders) and their risk factors in people living with HIV?
3. What are the current models/patterns of accessing care for HIV and associated chronic conditions?
4. How satisfied are PLHIV with the current standard and model of HIV care?
5. How prevalent is HIV-related stigma and discrimination experienced by people with HIV?

The project aims to make the survey a repeat cross-sectional survey of healthcare needs and sexual behaviour in HIV positive individuals conducted every three years. The results of this project will provide valuable insights that will be generalisable to the wider HIV positive community. The data will be used to inform HIV prevention programmes and by commissioners to evaluate and fund HIV specialist services.

The project is being carried out in three phases. Phase 1, the formative phase, took place from January 2013 to December 2013, and used mainly qualitative methods with participants and clinics to develop and refine the survey tool and explore the acceptability and feasibility of a variety of incentives for targeting clinics and potential participants in order to improve survey response rates. Phase 2, the pilot phase, took place from January 2014 to July 2015, and was piloted in 30 clinics which were randomly allocated to one of four combinations of interventions in a factorial design aimed at optimising participation and feasibility of delivery.

In the current phase, Phase 3, we will employ the optimal delivery strategy on a national scale and invite a random sample of PLHIV attending 74 HIV clinics to complete the survey.

D. Project Timeline



E. Methods

1. Study Design

This is a multi-site, cross-sectional questionnaire study in a random sample of adults living with HIV attending outpatient NHS HIV specialist clinics in England, Wales and Northern Ireland.

2. Setting

The questionnaire study will take place in 74 HIV outpatient clinics across England, Wales and Northern Ireland (see Appendix 7).

3. Study Population

The study aims to recruit a representative sample of people living with HIV from outpatient HIV specialist services.

3.1. Inclusion Criteria

- HIV positive
- Aged 18 and over
- Resident and accessing outpatient NHS HIV clinics in England, Wales, and Northern Ireland
- Reported to SOPHID in the previous calendar year

3.2. Exclusion Criteria

- Unable to complete online questionnaire due to language or literacy

4. Sample Size

Positive Voices primarily aims to provide population-level point and prevalence estimates. Therefore precision levels (i.e., one-sided 95% confidence interval) were the criterion for determining sample sizes, as opposed to power levels which are used for hypothesis driven studies.

A simple sample size calculation was performed to estimate the total number of questionnaire responses needed to answer the main study questions. The sample size calculation was performed on several outcomes, favouring a more conservative sample size. The outcome selected for the final calculation was prevalence of depression-anxiety, a common non-communicable disease in PLHIV. Using the weighted prevalence from the pilot of 29.6%, a one-sample comparison of proportion test was performed. With a significance level of 5% and a precision of 3%, we require **891 participants**.

A design effect (DE) adjustment was applied to account for clustering within the 74 participating clinics using the equation: $DE = 1 + \{(cv^2 + 1)m - 1\}\sigma$

Where m = mean cluster size (m= 41, using known cluster sizes from SOPHID 2015), CV is the coefficient of variation (CV=1.25 [given standard deviation of cluster size = 51.5]) and σ is the intra-cluster correlation coefficient (ICC) estimated at 0.02. The DE multiplier was calculated to be 3.1. An iterative process was done to balance the sum of patients individual cluster sizes and the sample size calculation, and the final recruitment target was **3,048** in order to produce an accurate population estimate (minimum sample size required 2,755).

This sample size was further inflated to account for non-response, so calculating the e total number of patients needed to sample from each clinic. In the pilot study, 6% of patients declined the survey outright, and a further 10% were non-recruitable*. Of those who accepted the survey, the response rate was 25%. Several measures have been added in Phase 3 to improve response rate including a choice of paper or online interview format and a £5 gift voucher incentive. Applying the decline rate from the pilot, the non-recruitable rate, and a response rate of 30%, a total of **11,967** HIV patients must be selected to achieve the recruitment target.

Appendix 7 shows the number of patients required to sample ("Patient Sample") and the required sample ("Completed Questionnaires") for each participating clinic.

**Deceased (1%); no longer attending clinic or lost to follow-up (7.6%); prisoners (0.4%); and invalid clinic's patient number/never seen at this clinic (1%)*

5. Sampling Methods

5.1. Site selection

Sites have been identified through the SOPHID reporting network. All HIV clinics reporting to SOPHID in 2015 (n=213) were invited to participate by email. Any HIV clinic expressing interest within one month of the email was included as a study site. Appendix 7 shows the list of participating clinics.

5.2. Participant selection

A probabilistic sampling strategy will be used to select a random sample of PLHIV to complete the questionnaire. The most recent year's SOPHID (2015) records from participating clinics will be extracted.

Using STATA, a random sample of patients will be selected from each study site (see "Patient Sample" in Appendix 7). Selected patients will be assigned a unique identifier (the "Survey Access Code") by PHE, which will be used to access the online questionnaire, will be printed on paper questionnaires and will ultimately link questionnaire data to national surveillance (SOPHID) records. Survey packs will be generated (see 6.3) and sent from PHE to study sites for distribution.

6. Study Documents

Prior to starting recruitment, PHE will provide each study site with the full study materials:

6.1. Site file

PHE will provide a site file with the following documents:

Document	**Number of copies**
Study Protocol	1
Manual of Operations	1
Quick Start Guide	5
Participant Information Sheet	5
Questionnaire Booklet	5
Freepost envelope	5
Study Log	1
Advance letter	1
Reminder letter	1
Postal cover letter	1
Pre-paid envelopes addressed to PHE	10
Labels for clinic notes	1 per patient
Posters for waiting room	3
End of Study Returns Form	1

6.2. Electronic files

PHE will provide a memory stick with electronic copies of the full study documentation, including the Study Log (see 10.1) in Excel spreadsheet format.

6.3. Survey Packs

PHE will provide a predefined number of survey packs (see "Patient Sample" in Appendix 7). Survey packs will be in a sealed envelope labelled with the clinic's patient number, hospital name, and the unique identifier, and contain all the information a patient needs to complete the survey, including:

Contents of envelope
Questionnaire Booklet
Participant Information Sheet
Freepost envelope
£5 gift voucher

6.4. Incentive

All participants will receive a £5 gift voucher enclosed in their survey pack as a thank-you for their consideration. Study sites do not need to administer the incentive. A £5 gift voucher was chosen based on the results of Phase 1 and Phase 2 work. In Phase 1 qualitative interviews, patients expressed a preference for an incentive, either monetary or non-monetary, compared to no incentive. However, the monetary incentive was deemed preferable to non-monetary options, such as prize draws or charitable donations, as they were more tangible. In the Phase 2 pilot, a £200 prize draw was trialled with found no difference in response rates between those offered prize draw entry compared to those who were not (Kall 2015). A prize draw was selected for future sustainability of the survey with a limited budget. However these findings support results of a systematic review which found that even low-value monetary incentive produced higher responses rates than a non-monetary incentive (Edwards 2009). A non-conditional incentive was chosen because pre-paid incentives are preferable for ethical reasons and reduce administrative burden on study sites.

7. Site Initiation Visit

A site initiation visit (SIV) will take place, in person or by telephone, for each study site. During the site initiation, PHE will describe the study methods and discuss with the clinical and research team possible ways to organise recruitment and data collection.

Decisions at each study site will depend on factors, such as staffing, recruitment targets, and local research protocols. Therefore, leeway is given for study sites to adapt the protocol to their local situation as long as they can:

1. Ensure, as far as possible, that all patients selected for the sample are approached to participate, preferably in person
2. Ensure appropriate resources, such as staffing and a suitable private space, are allocated for recruitment and data collection to meet the local target for completed questionnaires

8. Recruitment

Recruitment will take place between November 2016 and June 2017. Clinics will be asked to start recruitment on a day of their choosing (after the SIV) and recruitment will continue until there are no remaining survey invitations, or for six months, whichever comes first.

8.1. Patient identification

When the survey packs and site file are received on site, local staff can identify selected patients from the clinic number and date of birth printed on the study log and the outer envelope of the survey pack. Local staff can decide the best approach for recruiting selected patients. PHE recommends starting by searching the appointments book/database to identify which patients have an appointment scheduled during the recruitment period (and on recruitment days), and plan to recruit these patients at their next appointment. For patients not scheduled to attend on the days when recruitment is planned, local staff can contact patients to schedule an appointment to attend clinic and collect their survey pack. Study labels are provided for clinic notes, and survey packs can be inserted into the notes or kept separate.

8.2. Pre-contact letter

A template letter is provided to post or email to patients in advance of their visit (Positive Voices Advance Letter.docx). The letter notifies patients that they will be approached about the study at their next appointment and allows them to plan time to complete the survey in the clinic, if they wish. The letter should be sent 1-2 weeks in advance of their appointment, to patients that have provided consent to such contact from the clinic.

8.3. Initial approach

Patients selected for the study will initially be approached by local clinical or research staff. When selected patients attend clinic, local staff will use the patient information sheet (Appendix 8) to briefly explain the aims of the study, available questionnaire formats, confidentiality issues and the expected

time needed to complete it. Scripts will be provided by PHE to ensure a standardized recruitment approach between clinics. If a patient accepts, they will be given their survey pack, which contains all the information required to participate.

If a patient declines, the survey pack will be retained in the clinic and not offered to any other patient. Declined surveys should be logged on the Study Log under "Recruitment Status" (see 10.1) and tick the "Decline" box on the outer envelope of the patient's survey pack. Declined survey packs will be returned to PHE at the end of the study.

If a patient would like more information about the study, they will be asked to take the survey pack with them, and to contact the Positive Voices team using the contact details inside. Posters and leaflets explaining the purpose of the study will be distributed to the participating clinics and various HIV patient organisations and web sites.

8.4. Reminder contact

A template letter is provided to post or email to patients that accepted the survey pack but did not complete the survey in-clinic (Positive Voices Reminder Letter.docx). The letter reminds patients about the survey and asks them to consider participating, if they have not already. The letter should be sent 1-2 weeks after their appointment, to patients that have provided consent to such contact from the clinic.

8.5. Non-recruitable patients

At every study site, around 1 in 10 patients will be non-recruitable. This is because the sample was drawn from the previous year's (2015) patient list, and patient status is always changing. Non-recruitable patients are defined as impossible to recruit for practical or ethical reasons, such as:

- Moved abroad
- Transferred care to another UK HIV clinic
- Lost to follow up (have not been seen in >12 months)
- Deceased
- Prisoners
- Vulnerable adults
- Any mental or emotional issue that would affect a patient's ability to consent

Local staff should review the study log and identify non-recruitable patients based on the criteria above. This should be done once at the start of recruitment, and again in the final weeks of the recruitment period.

Non-recruitable patients should be logged on the Study Log under “Recruitment Status” (see 10.1) and tick the “Non-recruitable” box on the outer envelope of the patient’s survey pack. Unused survey packs will be returned to PHE at the end of the study.

8.6. Post and Email recruitment

A facility is provided to recruit patients by post or email. This option can be used for:

- Patients not due to attend during the recruitment period, and cannot or do not wish to attend clinic in person to collect their survey pack
- Patients that, by the end of the recruitment period, did not attend the clinic as planned (e.g. missed appointments)
- Patients that request this option

A template cover letter is provided to accompany the survey pack (Positive Voices Reminder Letter.docx). For confidentiality reasons, PHE recommends that study sites contact patients by phone, email, or text to get permission to send the survey pack to a patient’s residence. For postal recruitment, a paper copy of this letter should be sent with the survey pack. For email recruitment, this letter and the participant information sheet should be attached to an email that contains the survey URL and the patient’s unique Survey Access Code. A step-by-step guide detailing the methods for post and email recruitment will be provided.

9. Consent

As is common practice for questionnaire studies, consent will be implied on completion of the survey itself. A participant information sheet is enclosed within the study packs which provides information about the survey and how to participate, risk and benefits, and contact information for the study team. Local staff will reiterate that the participation is voluntary and they should take time to decide whether or not to participate. There is no need for written informed consent.

10. Data Collection

The principal investigator at each study site should organise or delegate the following data collection responsibilities:

10.1. Maintenance of Study Log

At each clinic at which recruitment takes place, local staff will complete the study log after each day of recruitment. Study sites can complete either the paper or electronic study log. The study log will be prefilled with:

Clinic's patient number
Date of birth
Survey Access Code

Local staff will record the following information for each patient:

Recruitment status – Accepted / Declined / Non-recruitable
Date recruited
Mode of recruitment - In person / Post / Email
Completed in clinic? Yes / No
Advance Letter sent? Yes / No
Reminder Letter sent? Yes / No
Comments

Study sites are responsible for emailing or posting the study log to PHE each month.

10.2. Administering questionnaires

The Positive Voices questionnaire is self-administered and will take patients around 20 minutes to complete.

PHE has provided two questionnaire formats to choose from: paper or online (from any device with internet access). To complete on paper, fill out the questionnaire booklet and seal inside the enclosed envelope. The envelope has a Freepost label for postal return if completed outside the clinic. To complete online, enter the URL printed on the cover of the questionnaire booklet (www.ucl.ac.uk/voices), click the "Take Survey Now!" button, and enter the Survey Access Code (printed on the booklet cover) when prompted. The online survey is optimised for smartphones and tablets.

Patients can complete the questionnaire in the clinic, or take the questionnaire away and complete at their convenience. For optimal response rates, patients should be encouraged to complete the questionnaire in the clinic, either before or after their appointment (depending on what is convenient for the patient and/or feasible at each study site).

Each study site will need to consider whether private or screened areas are necessary and can be made available to those participants completing the questionnaires. Local staff should ensure completed paper questionnaires are placed in sealed envelopes and returned in the box provided.

10.3. Secure storage and transfer of data

Paper questionnaires and the study log must be stored securely within the clinic. Study sites are responsible for returning completed questionnaires to PHE each month (see Section H). Sites can either return questionnaires by post using the envelopes provided by PHE, or by courier. If a courier is required, sites are responsible for communicating this request to the study team and making the questionnaires available for collection by courier.

11. Data Management and Analysis

11.1. Data entry

Questionnaire data will be collected on either paper booklets or online survey software (SnapSurvey Inc). When paper questionnaires are received at PHE, they will be entered into an appropriate data entry package. An electronic .CSV file of the online questionnaire data will be extracted. Both files will be imported into STATA 13 (College Station, TX: StataCorp LP) and merged to create a master questionnaire data file.

11.2. Linkage

The master questionnaire data file will be linked to national surveillance records (SOPHID) using a lookup table that contains the unique identifier ("Survey Access Code"), the clinic's patient number, and the SOPHID record number. A minimum SOPHID dataset will be extracted containing residence, ARV treatment information, and CD4 and viral load data.

11.3. Weighting

The dataset will be manipulated to ensure it is representative of the national population of people in HIV care. First, sampling weights will be applied to adjust for unequal probability of selection at each clinic. Secondly, post-stratification will align the demographic profile of the survey respondents to match

the demographic profile of the 2016 SOPHID population on age, sex, sexual orientation, ethnicity and area of residence.

11.4. Analysis

Once the final dataset is created, all data management and analysis will done in STATA 13 (College Station, TX: StataCorp LP) on a dataset without personal identifiers. Population estimates will be calculated using the weighted data. Descriptive analysis and univariate analysis to explore the relationship between key variables will be conducted using t-test for normally distributed variables, Mann-Whitney test for non-normally distributed variables and chi-square test for categorical variables. Proposals for more detailed statistical analysis will be reviewed by the Positive Voices Study Team for approval.

F. Site monitoring

Study sites will receive regular updates from the Positive Voices study team about recruitment progress and response rates. Later in the study they will also be sent feedback on data completeness and quality. Sites will be responsible for communicating with the study team regarding study progress and any problems identified.

G. Data Security

The outer envelope of the survey pack and the study log will contain the following patient identifier: clinic's patient number. The study log will additionally include the patient's date of birth. This is to identify the selected patient back to the clinic. The paper questionnaire will contain a unique identifier ("Survey Access Code") generated by PHE, and this will be the only identifier used to link the questionnaire to national surveillance records. The lookup table with the unique identifier, clinic's patient number and SOPHID record number will be kept secure and separate from other data files and all analyses will be conducted without any patient identifiers. Paper questionnaires may have personal contact details provided by patients if they consent to be contacted to take part in future research (see Section I), and will be transported to PHE by recorded post or courier to each study site on a monthly basis. Patient contact details will be stored in a table in a dedicated, password protected Access database that is only accessed by the study team. Paper questionnaires will be stored securely in a locked cabinet at PHE for a maximum of 10 years and then destroyed. The online questionnaire is hosted on a secure HTTPS connection and data are encrypted at the point of transmission and stored at

rest on a secure, dedicated virtual server hosted at PHE. The study log will be password-protected and emailed over a secure connection to PHE on a monthly basis.

The data will be securely held at the HIV & STI Department, National Infection Service, Public Health England. All databases will be encrypted and password protected and the password only available to team members. Data collection, storage and use will be consistent with the procedures described in the NHS Information Governance Toolkit.

H. Confidentiality and Data Handling

HIV is a sensitive research topic and it is important to ensure that patient confidentiality is maintained. The questionnaire will be sent through a secure web server and the data encrypted and held centrally on a password protected database at Public Health England. Participants will be assigned a unique study identifier, and participants will not be asked to provide identifiable information for the pilot survey. At the end of the survey, participants are given the option to provide their personal contact details (first name and either their phone number or email address) if they consent to be contacted for future research. If they consent to this contact, this information will be unlinked from their survey data and will be stored securely on a separate password protected database at Public Health England.

All researchers involved in data linkage have been trained in handling data according to Caldicott guidelines and Section 60 of the Health and Social Care Act. All researchers are aware of the Data Protection Act 1998 and the need to maintain absolute confidentiality.

I. Ethics and Consent

This study has been reviewed by the London – Harrow Research Ethics Committee (13/LO/0279). The project will be subject to NHS Research and Development approval at each participating site before any study procedures are undertaken.

The survey pack will include a patient information sheet (Appendix 8). Consent for participating in the study will be implied by voluntary completion of the questionnaire. Patients are therefore given an opportunity to opt out of participation in this study.

J. Dissemination of Results

The results of the study will be disseminated first in a PHE report. We will also disseminate the results on a study webpage, through peer reviewed scientific journals, presentation at conferences, institutional websites, and via HIV focussed websites like NAM, HIV Treatment Update.

The study is, in part, the subject of a PhD thesis (to be submitted by Ms Meaghan Kall).

K. Future work

If shown to be feasible, the survey methodology will provide an infrastructure for obtaining further information from a representative sample of PLHIV under care. The survey can be repeated with a new sample at intervals, allowing analysis of changes over time in the population. It is also possible to repeat the survey in the same participants, to provide data for longitudinal analyses. Additional or alternative questions can be added to subsequent rounds of the survey to address further or differentenquiry. The anonymised dataset will be made available to collaborating researchers subject to an application being made to, and approved by, the Advisory Group for Behavioural Surveillance of People Living with HIV.

L. Funding

Phase 1 and 2 of this project was funded by a research grant from the NIHR Centre for Public Health Research. Phase 3 will be supported by Public Health England and funded by an unrestricted research grant from Gilead Sciences Inc.

References

Health Protection Agency (2010). *HIV in the United Kingdom: 2010 Report*. London: Health Protection Agency.

Friis-Moller N, Smieja M, Klein D (2008). Antiretroviral therapy as a cardiovascular disease risk factor: fact or fiction? A review of clinical and surrogate outcome studies. *Curr Opin HIV AIDS*, **3**: 220-5.

Thiebaut R, El Sadr WM, Friis-Moller N, Rickenbach M, Reiss P, Monforte AD, *et al* (2005). Predictors of hypertension and changes of blood pressure in HIV-infected patients. *Antivir Ther*, **10**: 811-23.

De Wit S, Sabin CA, Weber R, Worm SW, Reiss P, Cazanave C, *et al* (2008). Incidence and risk factors for new onset diabetes in HIV-infected patients: the Data Collection on Adverse Events of Anti-HIV Drugs (D:A:D) study. *Diabetes Care*, **31:** 1224-9.

Worm SW, De Wit S, Weber R, Sabin CA, Reiss P, El Sadr W, *et al* (2009). Diabetes mellitus, pre-existing coronary heart disease, and the risk of subsequent coronary heart disease events in patients infected with human immunodeficiency virus: the Data Collection on Adverse Events of Anti-HIV Drugs (D:A:D Study). *Circulation*, **119**: 805-11.

Evans H, Tsourapas A, Mercer CH, Rait G, Bryanet S (2009). Primary care consultations and costs among HIV positive individuals in UK primary care 1995-2005: a cohort study. *Sex Transm Infect*, **85**: 543-9.

Public Health England (2012). *Accessing Care - National HIV Tables, 2011*. Available at: http://www.phe.gov.uk/webc/HPAwebFile/HPAweb_C/1221482342808

Shickle D (2010). *HIV health inequalities – why we need to better understand people who live with HIV.* University of Leeds, personal communication.

Richie J and Spencer L (1994). *Qualitative data analysis for applied policy research*. Bryman and Burgess, eds., Analysing Qualitative Data. London: Routledge.

Edwards PJ, Roberts I, Clarke MJ, Diguiseppi C, Wentz R, Kwan I, *et al* (2009). Methods to increase response to postal and electronic questionnaires. *Cochrane Database Syst Rev*, **3**: MR000008.

Porter SR, Whitcomb ME (2003). The impact of lottery incentives on student survey response rates. *Research in Higher Education*, **44(4)**: 389-407.

Appendix 1 – Phase 3: National survey clinics and sample size

Site	Site Code	Eligible patients*	Patient Sample	Completed questionnaires	% of SOPHID
Chelsea and Westminster Hospital	LONDOC&W	4386	878	222	5.1%
Mortimer Market Centre	LONDOMORT	4269	854	216	5.1%
Royal Free Hospital	LONDOFREE	3150	662	167	5.3%
St Mary's Hospital	LONDOMARY	3035	668	169	5.6%
Isleworth Hospital?	LONDOVICT	2984	687	173	5.8%
Royal London Hospital	LONDOROYBART	2574	618	156	6.1%
King's College Hospital	LONDOKINGS	2236	537	136	6.1%
Royal Sussex County Hospital	BRIGTROYSX	2112	507	128	6.1%
North Manchester General Hospital	MANCHNMAN	1596	384	97	6.1%
St George's Hospital	LONDOGEO	1492	359	91	6.1%
Queen Elizabeth Hospital, Birmingham	BIRMISELLY	1378	331	84	6.1%
Queen Elizabeth Hospital, London	LONDOWOOL	1009	243	62	6.1%
Homerton Hospital	LONDOHOM	999	240	61	6.1%
Newham University Hospital	LONDONEWH	996	240	61	6.1%
Leeds General Hospital	LEEDSGEN	990	238	60	6.1%
Birmingham Heartlands Hospital	BIRMIEAST	987	237	60	6.1%
Royal Liverpool University Hospital	LIVERROY	987	237	60	6.1%
Southmead Hospital	BRISTSOUTH	972	234	59	6.1%
Royal Hallamshire Hospital	SHEFFHALLM	828	199	51	6.2%
Barking Hospital	BARKIHOSP	818	197	50	6.1%
Royal Victoria Infirmary	NEWUTYNE	731	176	45	6.2%
Lewisham Hospital	LONDOLEWIS	703	169	43	6.1%
Charing Cross Hospital	LONDOCHX	689	166	42	6.1%
Royal Bournemouth Hospital	BOURNROY	650	156	40	6.2%
Northampton General Hospital	NORHAGEN	600	144	37	6.2%
Nottingham City Hospital	NOTTICITY	545	131	33	6.1%
Upton Hospital	SLOUGUPT	537	129	33	6.1%
Whipps Cross University Hospital	LONDOWHIPX	518	125	32	6.2%
Royal Berkshire Hospital	READIBERKS	496	120	30	6.0%
Cardiff Royal Infirmary and Cardiff University	CARDIROY + CARDIUNIV	649	156	40	6.2%
Manor Hospital	WALSAMAN	410	99	25	6.1%
Addenbrooke's Hospital	CAMBRADD	398	96	25	6.3%
Watford Clinic	WATFOGEN	394	95	24	6.1%
Norfolk and Norwich University Hospital	NORWINORFO	393	95	24	6.1%
West Middlesex University Hospital	ISLEWWMIDX	372	90	23	6.2%
James Cook University Hospital	MIDDLGEN	371	90	23	6.2%
Bradford Royal Infirmary	BRADFTRIN	364	88	23	6.3%
Gloucester Royal Hospital	GLOUCROYAL	352	85	22	6.3%
Southend University Hospital	WESTCSOUTH	352	85	22	6.3%
Derriford Hospital	PLYMODERR	291	70	18	6.2%
Great Western Hospital	SWINDMARG	237	57	15	6.3%

St Peter's Hospital	CHERTPETE	234	57	15	6.4%
Lister Hospital	STEVELIST	224	54	14	6.3%
Peterborough City Hospital	PETERDIST	216	52	14	6.5%
Royal Gwent Hospital	NEWPOGWENT	206	50	13	6.3%
Princess Alexandra Hospital	HARLOPRINA	193	47	12	6.2%
Worthing Hospital	SHORESOUTH	189	46	12	6.3%
Castle Hill Hospital	COTTICAST	179	43	11	6.1%
Ipswich Hospital	IPSWIHOSP	177	43	11	6.2%
Darent Valley Hospital	DARTFDAREN	167	41	11	6.6%
York Hospital	YORKYDIST	154	37	10	6.5%
Broomfield Hospital	CHELMJOHN	150	36	10	6.7%
Kent and Canterbury Hospital	CANTEKENT	139	34	9	6.5%
Hinchingbrooke Hospital	HUNTIHINCH	133	32	9	6.8%
West Suffolk Hospital	BURYSWEST	115	28	7	6.1%
Northgate Hospital	YARMOJAMS	115	28	7	6.1%
Kettering General Hospital	KETTEGEN	112	27	7	6.3%
Rotherham District General Hospital	ROTHEDGH	109	27	7	6.4%
Queen Elizabeth Hospital, King's Lynn	KINGLQUEEN	106	26	7	6.6%
Queen's Hospital	BURTODIST	104	25	8	7.7%
William Harvey Hospital	ASHFKWILL	101	25	7	6.9%
Queen Elizabeth The Queen Mother Hospital	MARGAQEQMH	99	24	6	6.1%
Hull Royal Infirmary	HULLCONIF	92	23	6	6.5%
Weymouth Hospital	WEYMODIST	81	22	6	7.4%
Hertford County Hospital	HERTFORD	75	21	6	8.0%
Tameside General Hospital	ASHTONTAME	73	21	6	8.2%
Harrogate District Hospital	HARRODIST	71	21	6	8.5%
Salisbury District Hospital	SALISGEN	64	20	5	7.8%
Royal Victoria Hospital	FOLKEROY	58	18	5	8.6%
Grimsby Sexual Health Centre	GRIMSBYHC	43	14	4	9.3%
Sir Robert Peel Community Hospital	TAMWORTH	40	14	4	10.0%
St Mary's Hospital, Isle of Wight	NEWPWSTMAR	35	13	4	11.4%
Scarborough General Hospital	SCARBHOSP	31	13	4	12.9%
Scunthorpe General Hospital	SCUNTGEN	31	13	4	12.9%
	TOTAL PATIENTS	**51923**	**11967**	**3048**	

* Aged 18+, Resident in England, Wales or Northern Ireland, and alive at 31/12/2015

Appendix 2 – Phase 3: Participant Information Sheet

Public Health England

UCL Imperial College London

PARTICIPANT INFORMATION SHEET

Positive Voices is a national survey of the lives, experiences, and health care needs of people living with HIV in the United Kingdom. We are asking you to take part in the survey to help improve health services, inform HIV policies, and identify the unmet needs of people with HIV.

Your answers will be kept strictly confidential and no-one looking at the study findings will be able to identify you in any way.

This study is being carried out by Public Health England (PHE), University College London (UCL) and Imperial College London and is funded by Public Health England and Gilead Sciences Inc.

Your participation is voluntary, so take time to decide, whether or not you wish to take part.

More information about the survey can be found online at www.ucl.ac.uk/voices.

Thank you.

Positive Voices: the National Survey of People Living with HIV

Why have I been invited?

You have been invited to complete the survey as you are an adult living with HIV and attended an NHS clinic in the past year. We invite you to share your unique experience and contribute to the improvement of HIV prevention, treatment, and care services.

How do I take part?

You can complete the survey online or on paper. Instructions can be found on the enclosed Questionnaire Booklet. To complete online, you will need a device with internet access and the access code on the front of your questionnaire booklet. To complete on paper, simply complete the enclosed questionnaire and return in clinic or using the prepaid-postage envelope. The survey will take about 20 minutes to complete, but it may take less or more time for some people. You can skip any questions you do not want to answer, and you are free to quit the survey at any time.

Why should I take part in the survey?

Positive Voices is the first national, large-scale survey of people living with HIV, which aims to collect data that represents the wider HIV community. The survey asks about a range of issues, such as medical conditions other than HIV, your overall health and quality of life, met and unmet

health and social needs, satisfaction with NHS services, education and employment, sex and sexuality, alcohol and drug use, adherence to HIV medication, HIV stigma and discrimination,

These data will provide valuable insights into the issues that most affect the health and lives of people with HIV. The results of the survey will be used to monitor and improve existing HIV services and policies, and to support the provision of new services.

Do I have to take part?

You do not have to take part in the survey. Accepting the survey pack from the clinic staff does not mean that you have to participate in the survey. If you choose not to take part, your healthcare and legal rights will not be affected in any way. If you decide to take part, you can quit the survey at any time.

Will my answers be kept confidential and anonymous?

Yes. The information you provide is totally confidential and handled in accordance with the Data Protection Act 1998. Your answers are anonymous and will not allow you to be identified in any way. Your doctors and clinic will not see your answers, and your response will not affect your care in any way. The personal access code on the cover of your questionnaire booklet will be used to link your answers to information already collected by Public Health England, such as CD4 and viral load results. This will give insights into how lifestyles and experiences can affect health. This information, as well as your responses, is completely anonymous. For more information on Public Health England's national HIV surveillance, go to: https://www.gov.uk/government/collections/hiv-surveillance-data-and-management

Data Security

Survey data will be held securely in the HIV/STI Department at Public Health England, with access restricted to members of the study team. Data storage and use is subject to the security and confidentiality requirements governing Public Health England's collection of HIV surveillance data, as per the Data Protection Act 1998 and Section 60 of the Health and Social Care Act. All members of the study team have been trained in handling sensitive data according to Caldicott Guidelines and are required to maintain absolute confidentiality.

Gift Voucher

A £5 High Street Voucher is enclosed as a gift from Public Health England in appreciation for your interest. This is yours to keep whether or not you wish to take part. See the conditions on reverse for where the voucher can be used. At the end of the survey, you will be asked to consent for the researchers to link your survey responses to prescribing data at your HIV clinic. You will also be invited to provide contact details to take part in future research. If you do not wish to take part, skip these questions. Your questionnaire is still useful.

What do I do if I have questions or complaints about the survey?

Please contact the researchers using the details below:

Chris Farey, Survey Administrator or Carole Kelly, Senior Scientist

HIV/STI Department, National Infection Service, Public Health England, 61 Colindale Avenue, London NW9 5EQ

Email: positive.voices@phe.gov.uk

Phone: 0208 327 7566 or 0208 327 6727

If you wish to make a formal complaint you can call patient support services at Camden PCT on 020 3317 3003, or email pss@camdenpct.nhs.uk.

This research has been reviewed and approved by the London Harrow NHS Research Ethics Committee (Project ID 13/LO/0279).