Public Health England

UCL Imperial College London

Positive Voices
the national survey of people living with HIV

MANUAL OF OPERATIONS FOR STUDY SITES

1. Project summary

Positive Voices is a new national, large-scale, web-based survey which aims to collect data from a representative sample of people living with HIV on a range of issues which affect their health including: education and employment, sex and sexuality, alcohol, tobacco and drug use, adherence to HIV medication, quality of life, HIV stigma and discrimination, and satisfaction with NHS services.

The survey will complement existing clinical surveillance of people with HIV, and will provide valuable insights about living with HIV and the epidemiology of HIV in the UK. The results will be used to evaluate and inform improvements to HIV services as well as support the provision of new services.

2. General information

2.1. Study design

Positive Voices is a multi-site, cross-sectional questionnaire study of a random sample of adults living with HIV attending outpatient NHS HIV specialist clinics in England and Wales. All participants receive a **£5 gift voucher**, enclosed in their **Survey Packs**, as a thank-you for considering taking part. This national survey will be conducted in **74 HIV clinics** and aims to recruit between **3,000 and 4,000 patients** in total, over a **six-month period**.

2.2. Study website

The survey can be accessed at the website: **http://www.ucl.ac.uk/voices**. All information and study documents are also available on this website.

2.3. Study management

The Study Team include Dr. Valerie Delpech (PHE), Dr. Richard Gilson (UCL), Dr. Maryam Shahmanesh (UCL), Dr. Anthony Nardone (PHE), Meaghan Kall (PHE), Chris Farey (PHE) and Carole Kelly (PHE). The survey was developed under the guidance of an Advisory Group, including: Professor Graham Hart, Professor Jane Anderson, Dr. Ann Sullivan, Dr. Cath Mercer, Yusef Azad, Jess Peck, Professor Jackie Cassell, Julie Musonda, Dr. Alan McOwan, Jane Bruton, Michelle Croston, Professor Jonathan Elford, Larry Gurney, and Professor Helen Ward.

2.4. Contact information

General enquiry email address:
positive.voices@phe.gov.uk

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2.5. Funding and ethics

The study is coordinated by PHE and funded by PHE and Gilead Sciences Inc. and has been reviewed and approved by the London Harrow NHS Research Ethics Committee (Project ID 13/LO/0279).

3. Planning and preparation for the study

3.1. Patient selection

PHE will randomly select records of reported HIV infected individuals for each clinic from their national public health surveillance dataset. Patients aged 18 and over, resident in England or Wales, reported to be living at the end of 2015, and have a **clinic ID** on file will be eligible for selection. Therefore the number of patients participating in each site has been pre-determined and the total number of selected patients within each clinic has been listed in **Appendix 1** of this document.

3.2. Delivery of study documentation and materials

Individuals will be identified by their **clinic ID and DOB** as well as a **unique identifier** (the '**Survey Access Code**') assigned by PHE**.** In addition to a hard-copy in the site file, PHE will provide each site with an electronic copy of their list of selected patients, in Microsoft Excel format, in the form of a **Study Log** which will be used for recording the status of each patient's recruitment.

PHE will provide each site with a **Site File** containing hard copies of the following study documentation that can be used by the clinic as reference:

- 1 x copy of three patient letters:
    - **Advance letter**
    - **Reminder letter**
    - **End of Study letter**
- **Labels** for each participant's clinic notes
- 1 x Positive Voices **Phase 3 Protocol**
- 1 x **Manual of Operations**
- 3 x laminated **Quick Start Guides**
- 3 x **Participant Information Sheet** (spare, for patients)
- 3 x **Questionnaire Booklet** (spare, for patients)
- 3 x **A5 pre-paid envelopes** addressed to PHE (spare, for patients)
- 10 x **A3 large pre-paid envelopes** addressed to PHE (for clinic use)
- 2 x **posters** for the waiting room
- 1 x **End of Study Returns Form**

A USB **memory stick** with electronic copies of all these documents, including the **Study Log,** will also be sent to each clinic. PHE will also provide one personalised **Survey Pack** for each selected patient. **Survey Packs** are sealed envelopes labelled with the **hospital name, clinic ID**, and **unique identifier** (the **'Survey Access Code'**), and contains all the information needed to complete the survey including:

- **Questionnaire Booklet**
- **Participant Information Sheet**
- **Pre-paid envelope**
- **£5 gift voucher**

Patients must only be given the Survey Pack with their clinic ID on the outside. All participants will receive the **£5 gift voucher** enclosed in their enclosed pack as a thank you for their consideration. This will be theirs to keep whether or not the patient wishes to take part. Study sites do not need to administer the gift voucher..

3.3. Site initiation visit (SIV)

Once necessary approvals are in place, a site initiation visit (SIV) with the Study Team can be arranged either by teleconference or in person. During this meeting, the study methodology will be described and the possible ways to organise recruitment of participants and data collection within each individual setting will be discussed.

Decisions made 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:

- Ensure, as far as possible, that all selected patients are approached to participate, preferably in person
- Ensure appropriate resources, such as **staffing** and a **private or screened area** for those participants completing the paper questionnaire, are made available for recruitment to meet the local site target for numbers of patients participating.

4. Recruitment

After the SIV, clinic can choose a convenient date to start recruiting participants. All sites will be given 6 months to recruit patients and the study will close on **31st August 2017**. Each site should continue recruiting until all the survey packs are handed out or **six months** after the date that the first patient was recruited – whichever comes first. Posters publicising the survey will be provided for clinic waiting rooms.

4.1. Pre-contact letter

A template letter is provided in the site file for posting or emailing to patients before their visit to the clinic (**Positive Voices Advance Letter.docx**). The letter can be used to notify patients, one to two weeks in advance of their appointment, that they will be approached about the study at their next visit. This will allow them to plan for time to complete the survey in the clinic, if they wish. The letter should only be sent to patients that have previously provided consent to such contact from the clinic.

4.2. Issuing Survey Packs

Patients should ideally be invited to complete the questionnaire in-person at the HIV clinic when they attend for a routine appointment, by a member of research or clinic staff. **In order to ensure a good response rate, patients should be encouraged to complete the questionnaire in the clinic**, although they may opt to take the **Survey Pack** away and complete it online or return the paper copy using the enclosed **pre-paid envelope**.

When selected patients are approached, a summary of the study should be given briefly along the following lines:

"Our clinic is participating in a survey about the health and needs of people with HIV. You have been invited to take part in the survey. All the information you need is inside this envelope. Please read the information and take time to decide whether or not you want to participate."

The **Participant Information Sheet** and **Quick Start Guide** can be used to discuss further patient queries, such as how to complete the **questionnaire** (online or on paper), where to return completed questionnaires, how long it will take (~20 minutes) and any questions about confidentiality and how the data will be used. If the patient has further questions, they can be referred to the study website, or directly to the **Study Coordinator** at PHE.

If a patient **accepts**, the correct **Survey Pack** should be issued containing the **Questionnaire Booklet** with their **clinic ID** on the front and a pen. Direct the patient to an appropriate area to complete the questionnaire and remind them to seal the completed **Questionnaire Booklet** in the envelope provided. Patients should be instructed to **seal completed paper questionnaires** in the enclosed envelope. A **large labelled box** should be placed a prominent position in the clinic for collection of completed questionnaires. The questionnaire consists of approximately **100 questions** and will take around **20 minutes** to complete. Patients will

have a choice whether to complete the survey on **paper** or **online**. To complete **online**, the URL should be typed as printed on the cover of the questionnaire booklet (**www.ucl.ac.uk/voices**), and the "**Take Survey Now!**" button clicked, followed by entering the **Survey Access Code** (printed on the booklet cover) when prompted. The online survey has been optimised for **smartphones** and **tablets**. Tablets or iPads may be provided in the clinic to facilitate completion.

If a participant accepts the **Survey Pack** but does not wish to complete the questionnaire in the clinic, note this down in the **Study Log** and flag a **Reminder Letter** to be sent about returning the questionnaire (see Section 4.3). The **Survey Pack** contains a pre-paid envelope for postal return.

If a patient **declines**, the **Survey Pack** should be retained in the clinic and not offered to any other patient. Declined surveys should be noted in the **Study Log** and the "Decline" box ticked on the outer envelope of the patient's **Survey Pack**. Declined packs should be returned to PHE.

At the end of each day, all paper questionnaires should be collected from the box and stored securely, and the **Study Log** updated (see Section 5.1).

4.3. Reminder letter

A template letter is provided in order to post or email to patients that accepted the **Survey Pack** but did not complete the questionnaire onsite (**Positive Voices Reminder Letter.docx**). This letter reminds patients about the survey and asks them to consider participating, if they have not done so already. The letter should be sent one to two weeks after their appointment, to patients that have provided consent to such contact from the clinic.

4.4. Non-recruitable patients

At every study site, around one in ten patients will be **non-recruitable**. This is because the sample will be drawn from the previous year's patient list (2015), and patient status is changeable. **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 (not seen in >12 months)
- Deceased
- In prison
- Any mental or emotional issue that would affect a patient's ability to consent

Clinic 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 noted on the **Study Log** and the 'Non-recruitable' box on the outer envelope of the patient's **Survey Pack** should be ticked. Unused packs should be returned to PHE at the end of the study.

4.5. Post and email recruitment

A facility has been provided to recruit patients by post or email. This option should 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, have not attended the clinic as planned (e.g. missed appointments)
- Patients that request this option

The reminder letter (**Positive Voices Reminder Letter.docx**) should accompany the **Survey Pack**. For confidentiality reasons, PHE recommends that clinic staff contact patients by phone, email, or text to get permission to send the pack to a patient's residence. Once granted for postal recruitment, a paper copy of the letter should be sent with the **Survey Pack**. For email recruitment, the letter and the **Participant Information Sheet** should be attached to an email that contains the **survey URL** and the patient's **unique identifier** (the '**Survey Access Code'**).

PHE will reimburse all postage costs upon invoice at the end of the study.

5. Data collection

5.1. Responsibilities

The clinical lead at each study site should organise or delegate the following inter-dependent data collection responsibilities:

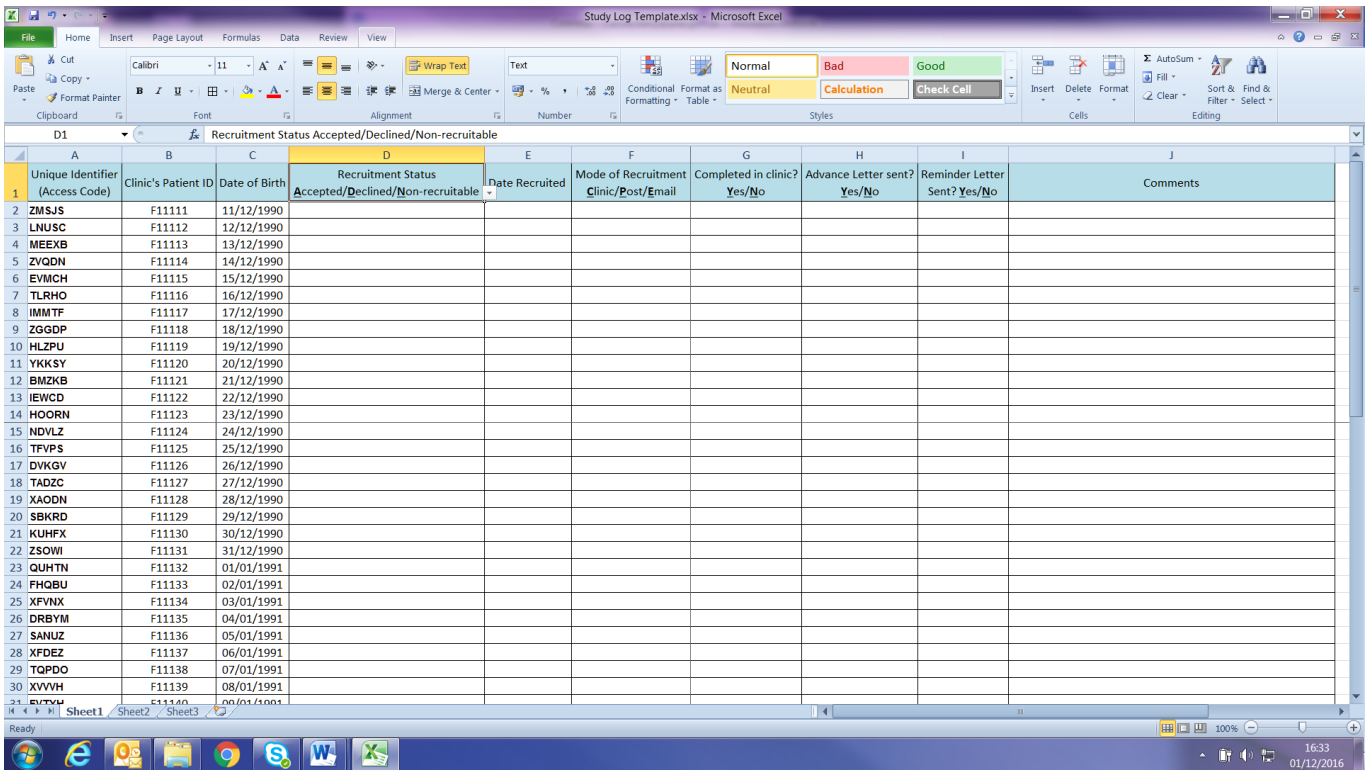
- Maintenance of the **Study Log**
- Secure storage and transfer of data to the study team

5.1.1. Maintenance of the Study Log

The **Study Log** is prefilled with a list of selected patients, identified by **clinic ID** and **date of birth**. The log tracks the recruitment status of each selected patient.

The **Study Log** also supplies the **unique identifiers** which are anonymised and used in the analysis of the data produced from the survey. The **Study Log** is the only document linking the **unique identifier** with the **clinic ID**. Each clinic will be able to access their own **Study Log** and is **confidential** to the study sites. It should be updated on a daily basis to keep track of all individuals approached to participate in the study, and further details of participation.

The **Study Log** is supplied as a structured Excel spreadsheet which is described in detail, with a full list of fields, in **Appendix 2** and looks like the figure below:



1. Study sites can maintain either the electronic or paper version of the **Study Log**.
2. For a patient who accepts the **Survey Pack**, the remaining fields of the **Study Log** should be entered, entering **A** for 'Accepted' in the Recruitment Status column and remembering to type any comments for the attention of the researchers.

3. For a patient who declines participation, only the Recruitment Status field of the **Study Log** should be entered by entering **D** for 'Declined'.
4. For a patient who is non-recruitable, only Recruitment Status field of the **Study Log** should be entered by entering **N** for 'Non-recruitable' and the reason provided in the Comment field.
5. At the end of each day of recruitment, study sites should ensure the **Study Log** is complete for all patients recruited whether accepted, declined or non-recruitable.
6. Study sites are responsible for emailing the **Study Log** to PHE at the end of each month.

5.1.2. Secure storage and transfer of data

Study sites should have secure physical areas for storage of:

- Completed paper **Questionnaire Booklets**
- Paper and electronic copies of the **Study Log**
- **Pre-paid envelopes**
- Memory sticks

At the **end of each month** (or periodically as agreed), the study sites should return the following to the **Survey Administrator**:

- Completed paper **Questionnaire Booklets**
- Unused (declined or non-recruitable) survey packs (unopened)

5.2. End of study returns

After six months, the study will be closed for recruitment. Within **one month** of this date, sites are asked to complete the following study closure procedures:

- Collect and count the remaining **Survey Packs** and enter this number into the **End of Study Returns Form** (You may request a list of patients that were not recruited from the **Survey Administrator** if this is helpful).
- Enter the date that the last patient was recruited, or that you stopped actively recruiting.
- Post the **End of Study Returns Form** along with all remaining **Survey Packs** to the **Survey Administrator** using the **pre-paid envelopes** provided. Sites can either return questionnaires by post using the envelopes provided by PHE, or by courier. If a courier is required, clinics should contact the **Study Team** with this request and make the questionnaires available for collection.

6. Study tasks

Before the study begins

- Decide how best to organise the recruitment of participants, ie. whether to call patients into clinic or wait for their next routine attendance, or a combination of these two approaches.
- Search appointment calendar/database to identify if the selected patients are scheduled to attend during the **six months** that the study will be recruiting and, if not, consider arranging appointments for those that are not booked in.
- Ensure that the **Survey Packs** are securely stored in the clinic
- Identify a suitable private space for participants to complete their questionnaire

During the study

- **Two weeks** in advance of each patient's appointment, send the **Advance Letter** by post or email to participants that have consented to receiving contact from the clinic
- When selected patients attend their clinic appointments, introduce the survey and distribute **Survey Packs**
- If any **Survey Packs** are lost or misplaced, spare **Questionnaire Booklets and Participant Information Sheets** are provided in the site file, and write in the **unique identifier** and **clinic ID** for that patient on the front of the questionnaire
- Tick the relevant **box** on the **Survey Pack** to record participants that have **declined** or are **non-recruitable** (as defined in 4.4)
- Encourage partipants to complete their questionnaire in the clinic
- Following completion, ensure that the completed **Questionnaire Booklets** are sealed in their envelopes and placed in a large box provided
- **Two weeks** after a clinic appointment, send the **Reminder Letter** by post or email to patients that have consented to receiving contact from the clinic, and who accepted the **Survey Pack** but did not complete onsite
- Record all recruitment activity in the **Study Log** (see **section 5.1**) on a **daily** basis
- Communicate with the **Study Team** regarding progress or issues arising

At the end of each month

- Email the **Study Log** to the **Survey Administrator**
- Return completed **Questionnaire Booklets** and unused **Survey Packs** to PHE (contact the **Study Team** to arrange courier)

Towards the end of the study

- In the **final weeks** of the recriutment period, identify patients that have not yet been offered the **Survey Pack.** Send the pack and the **End of Study Letter,** to patients that have previously consented to contact from the clinic

After the end of the study

- At the end of the recruitment period, review the patient list to identify selected patients that were **non-recruitable**, and tick the relevant box on the **Survey Pack**
- Complete the **End of Study Returns Form** and **post** it back to PHE, along with any remaining **Survey Packs** and **completed Questionnaire Booklets**

7. Computers and tablets, such as iPads, in clinic

Although participants can choose the **on-line** questionnaire, there is no requirement for it to be completed in the clinic, or for clinics to provide computers. However, PHE has a small number of iPads that may be made available on request (with priority given to larger sites). Sites that have computers or tablets available for patients should:

- Ensure the device has internet access (the survey will not work offline)
- Ensure the device is securely anchored to an immovable object
- Bookmark the study website: **www.ucl.ac.uk/voices.**
- Allow patients at least 20 minutes to complete the survey

8. Feedback and reports

Study sites will receive regular updates from the study team about recruitment and response rates. At the end of the study, each site will receive a report on their local results. Later on in the study they will also be sent feedback on data completeness and quality.

9. Regulatory requirements

It is the responsibility of each participating site to ensure that all necessary documents and approvals are obtained before enrolling patients in the study.

Appendix 1 – Positive Voices: clinics and sample size

Site	Eligible patients	Patient Sample	Target completed questionnaires
Chelsea and Westminster Hospital	4540	818	206
Mortimer Market Centre	4410	794	201
56 Dean Street	3419	684	173
Royal Free Hospital	3107	622	157
St Mary's Hospital	3101	621	157
Royal London Hospital	2632	580	146
King's College Hospital	2238	538	136
Royal Sussex County Hospital	2147	516	130
North Manchester General Hospital	1976	475	120
St George's Hospital	1509	363	92
Queen Elizabeth Hospital, Birmingham	1453	349	88
Leeds General Hospital	1420	341	86
Queen Elizabeth Hospital, London	1058	254	64
Homerton Hospital	1030	248	63
Southmead Hospital	1022	246	62
Birmingham Heartlands Hospital	1013	244	62
Royal Liverpool University Hospital	1003	241	61
Newham University Hospital	945	227	58
Barking Hospital	867	209	53
Royal Hallamshire Hospital	818	197	50
Royal Victoria Infirmary	765	184	47
Lewisham Hospital	744	179	45
Charing Cross Hospital	716	172	44
Royal Bournemouth Hospital	683	164	42
Cardiff Royal Infirmary and Cardiff University	664	160	41
Northampton General Hospital	607	146	37
Nottingham City Hospital	584	141	36
Royal Berkshire Hospital	521	126	32
Upton Hospital	511	123	31
Whipps Cross University Hospital	494	119	30
Norfolk and Norwich University Hospital	435	105	27
Watford General Hospital	422	102	26
Manor Hospital	412	99	25
Addenbrooke's Hospital	407	98	25
Gloucester Royal Hospital	387	93	24
James Cook University Hospital	386	93	24
West Middlesex University Hospital	378	91	23

Southend University Hospital	373	90	23
Bradford Royal Infirmary	369	89	23
Derriford Hospital	302	73	19
Castle Hill Hospital	288	70	18
Royal Gwent Hospital	266	64	17
Great Western Hospital	249	60	16
Peterborough City Hospital	238	58	15
St Peter's Hospital	231	56	14
Lister Hospital	226	55	14
Worthing Hospital	201	49	13
Ipswich Hospital	199	48	13
Princess Alexandra Hospital	191	46	12
Broomfield Hospital	180	44	11
Gravesham Community Hospital	179	43	11
Kent and Canterbury Hospital	163	40	10
York Hospital	151	37	10
Rotherham District General Hospital	146	36	9
Hinchingbrooke Hospital	136	33	9
Kettering General Hospital	136	33	9
Northgate Hospital	127	31	8
William Harvey Hospital	122	30	8
Queen Elizabeth Hospital, King's Lynn	108	26	7
West Suffolk Hospital	106	26	7
Queen's Hospital	99	24	6
Hull Royal Infirmary	96	24	6
Queen Elizabeth The Queen Mother Hospital	94	23	6
Weymouth Hospital	87	23	6
Harrogate District Hospital	81	22	6
Hertford County Hospital	70	20	5
Salisbury District Hospital	58	18	5
Sir Robert Peel Community Hospital	45	15	4
Royal Victoria Hospital	37	13	4
Scarborough General Hospital	34	12	3
St Mary's Hospital, Isle of Wight	32	11	3
Grimsby Sexual Health Centre	15	6	2
Scunthorpe General Hospital	8	4	1
TOTAL	54267	12114	3077

* Aged 18 or over, resident in England or Wales, and alive as at 31st December 2015

Appendix 2 - Study Log Details

The study spreadsheet called the **Study Log** is formatted for **Microsoft Excel 2010** (.xlsx). It will require you to enable editing.

The full set of fields in the **Study Log** spreadsheet is as follows:

Field	Purpose / Description	Characteristics
Unique identifier (Survey Access Code)	Anonymised patient ID	Prefilled and non-editable. 6 letter text string.
Clinic ID	Local patient identifier / hospital number	Prefilled and non-editable. Not to be transferred outside the clinic.
Date of birth	Patient's date of birth	Prefilled and non-editable.
Recruitment Status **Accepted/Declined/Non-recruitable**	Character defining recruitment status, either A for Accepted, D for Declined or N for Non-recruitable	Drop down menu.
Date Recruited	Date survey pack given to selected patient	In DD/MM/YYYY date format.
Mode of Recruitment **Clinic/Post/Email**	Character defining mode of recruitment, either C for routine appointment in clinic, P for contacted by post or E for contacted by email	Drop down menu.
Completed in clinic? Yes/No	Identify those who completed the questionnaire (on-line or paper) in the clinic	Drop down menu.
Advance Letter sent? Yes/No	Whether an Advance Letter was sent out to this patient	Drop down menu.
Reminder Letter sent? Yes/No	Identify whether an Reminder Letter was sent out to this patient	Drop down menu.
Comments	Any notes for the attention of the **Study Team**, including **reasons for Non-recruitable**	