

# Evaluation of resources to promote human immunodeficiency virus (HIV) testing in tuberculosis (TB) clinics

**Submission date**  
28/09/2009

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
17/12/2009

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
05/07/2013

**Condition category**  
Infections and Infestations

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1191942172940?p=1191942172940>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

Evaluation of information resources developed for 'human immunodeficiency virus (HIV) testing in tuberculosis (TB) clinics': a cluster randomised controlled step-wedged study

## Acronym

The NKS TB-HIV Evaluation Study

## Study objectives

The aim of this project is evaluate the implementation of recommendations from the British Human Immunodeficiency Virus (HIV) Association (BHIVA) guidelines on universal "opt-out" HIV testing for all individuals attending tuberculosis (TB) clinics and the value of information resources to support this. The guidelines recommends that all patients in TB clinics should be offered and recommended a HIV test irrespective of their age, and offer of the test is not based on an individual's risk factors.

The information material being evaluated in this study has been produced by a working group with representatives from Health Protection Agency (HPA), Primary Care Trusts, Chest Clinics, HIV services and voluntary organisations. The materials include information z-cards for patients, flip charts and leaflets for healthcare staff working in TB clinics. All these materials would be provided to the chest clinics free of charge.

To evaluate effectiveness of these leaflets we need to collect some information from the clinics over a 6-month period (August - January 2010). The data collection would include: London TB Register number, patients' initials and date of birth (DOB) (to check against LTBR number), and if HIV testing was offered and accepted with the date of test.

The material will be introduced to the clinics gradually and in a stepwise manner over 6 months. The order of allocation of clinics will be determined by computer generated random numbers. Clinics will receive resources at the allocated time over the next 6 months, this could be any time during the 6-month period of the evaluation project. However, we will collect the HIV testing data from all the clinics throughout this 6-month period to compare uptake rates before and after introduction of the leaflets.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

A formal enquiry was sent to the Camden and Islington Community Local Research Ethics Committee produced for this project. Application was submitted on the 24th March 2009 and a reply was received on the 23rd April 2009 confirming that this study is an evaluation of a health service and therefore does not require full ethical review.

## Study design

Multicentre cluster randomised controlled step-wedged trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Screening

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Tuberculosis, human immunodeficiency virus (HIV)

**Interventions**

Intervention:

Information resources developed to recommend and raise awareness on universal HIV testing in TB clinics include a z-card for patients, information leaflet for nurses and healthcare workers, a training session for health care staff and a table top information display (flip chart). These materials together with the introduction of a policy of opt-out testing will be the intervention.

Randomisation and allocation:

This will involve a sequential roll out of an intervention to TB clinics over a period of six months. A pair of clinics will be allocated to the intervention each month. By the end of the study all participating TB clinics would have received the intervention. The order in which the intervention is delivered will be determined using a computer generated random sequence. The unit of allocation is the TB clinic.

Masking:

Participants will not be blinded, however, the persons analysing the study will be blinded.

Data collection:

All participating clinics will provide data on uptake over the entire study period (before and after the introduction of the intervention). Data on the characteristics of clinics and anonymised information on patients/staff will be collected.

As this is a "step-wedged trial" the control group are all the clinics before implementing the 'opt out policy and intervention of resources'. Therefore the control group changes over the study period. The total duration of the trial is 6 months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Ratio of uptake of HIV testing before (control arm) and after intervention. Reasons for refusing to accept the offer of HIV test will be analysed. Measured on the 30th of every month until March 2010.

**Secondary outcome measures**

Cost effectiveness, measured at the end of the trial

**Overall study start date**

10/10/2009

**Completion date**

10/04/2010

## Eligibility

**Key inclusion criteria**

TB clinics in London and all TB patients (irrespective of their age and gender) attending these clinics within the time-frame.

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

20 - 25 TB clinics, approximately 1200 - 1400 patients

**Key exclusion criteria**

1. Individuals who do not consent
2. Patients attending the TB clinic but not diagnosed with TB

**Date of first enrolment**

10/10/2009

**Date of final enrolment**

10/04/2010

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**61 Colindale Avenue**  
London  
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## **Sponsor information**

**Organisation**  
Health Protection Agency (UK)

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**Sponsor type**  
Government

**Website**  
<http://www.hpa.org.uk/>

**ROR**  
<https://ror.org/03sbpja79>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Health Protection Agency (UK)

**Alternative Name(s)**  
HPA

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2013		Yes	No