# Dried blood spot testing in UK prisons

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
11/03/2011		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
18/05/2011	Completed	[X] Results	
<b>Last Edited</b> 28/07/2014	Condition category Infections and Infestations	[] Individual participant data	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Noel Craine

#### Contact details

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## Additional identifiers

#### Protocol serial number

Version 1

## Study information

#### Scientific Title

Cluster randomised controlled trial of dried blood spot testing in UK prisons

## **Study objectives**

An intervention using dried blood spot testing for blood borne viruses will increase the blood borne viral diagnostic testing rate in prisons. This is defined as the proportion of the monthly prison throughput who take up the offer of a diagnostic test for blood borne viral infection (either venepuncture pre-intervention or DBS post intervention).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

10/MRE09/23 Research ethics commitee for Wales

It was noted that as this research will not be taking place within the NHS and is not a clinical trial of a medicinal product for human use, it falls outside the remit of Research Ethics Committees as set out in the Governance Arrangements for NHS Research Ethics Committees (GAfREC). The members present agreed that has this study fallen within their remit it would have been given a favourable opinion. The National Offender Management system (NOMS) and Ministry of Justice were also contacted; both bodies were satisfied that the study did not need further consideration by themselves.

## Study design

Stepped wedge cluster randomised controlled trial

#### Primary study design

Interventional

## Study type(s)

Diagnostic

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

Blood borne virus infection [Hepatitis C, Hepatitis B, Human immunodeficiency virus (HIV)]

#### **Interventions**

- 1. Dried blood spot testing (DBS) for blood borne viral infection
- 2. Comparing DBS against standard venepuncture based testing
- 3. The planned intervention is the opt-in offer of DBS testing for blood borne viruses (BBV) infection to all inmates at reception
- 4. The test will be offered by clinically trained prison health staff (either prison doctors or senior nursing staff) in a confidential manner
- 5. Results will likewise be fed back to inmates requesting diagnostic testing in a manner that ensures both confidentiality and prevents deductive disclosure. Intervention thus the training of prison healthcare staff in BBV diagnostic testing and the dried blood spot test

### Intervention Type

Other

#### Phase

Not Applicable

## Primary outcome(s)

Change in blood borne viral diagnostic testing rate in prisons with introduction of DBS

## Key secondary outcome(s))

Epidemiological data on prison disease prevalence for ongoing mathematical modelling research

## Completion date

07/04/2012

# **Eligibility**

## Key inclusion criteria

Five UK prisons - all inmates offered intervention

### Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

### Age group

Adult

#### Sex

All

## Key exclusion criteria

Does not meet inclusion criteria

#### Date of first enrolment

07/04/2011

#### Date of final enrolment

07/04/2012

## Locations

### Countries of recruitment

United Kingdom

Wales

## Study participating centre Micobiology dept

Bangor United Kingdom LL57 2PW

## Sponsor information

## Organisation

Public Health Wales (UK)

### ROR

https://ror.org/00265c946

# Funder(s)

## Funder type

Government

### Funder Name

Public Health Wales (UK)

## **Results and Publications**

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?
Results article	results	01/04/2015		Yes	No