

**BHIVA** 

British HIV Association

# 2024 Spring Conference



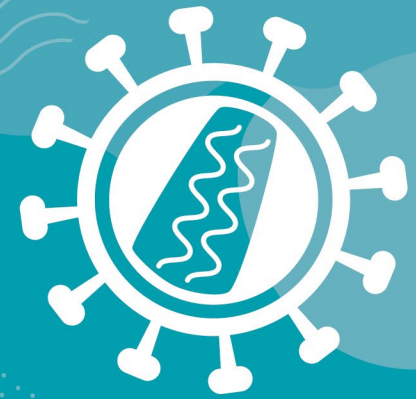
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**Mon 29<sup>th</sup> April – Wed 1<sup>st</sup> May**  
Birmingham, UK

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**TINIES Study: Validity of small volume blood testing  
for HIV viral load: Phase 1 results in participants  
with undetectable HIV viral load**

**Anya MacLaren**

UCL Centre for Clinical Research in Infection and Sexual Health, and  
Mortimer Market Centre (CNWL NHS Foundation Trust)



## Conflict of Interest

None Declared

Speakers are required by the Federation of the Royal Colleges of Physicians to disclose conflicts of interest at the beginning of their presentation, with sufficient time for the information to be read by the audience. They should disclose financial relationships with manufacturers of any commercial product and/or providers of commercial services used on or produced for patients relating to the 36 months prior to the event. These include speaker fees, research grants, fees for other educational activities such as training of health professionals and consultation fees. Where a speaker owns shares or stocks directly in a company producing products or services for healthcare this should also be declared.

## BACKGROUND

- Most people living with HIV attend clinic every 6 months for routine venepuncture blood tests
- New technology of small blood volume capillary testing (known as TINIES), can be used for routine biochemistry, full blood counts and HIV Ab / HBV sAg / HCV Ab testing
- Home testing is available for sexual health tests, however, TINIES is not validated for HIV viral load
- There is also no qualitative data on the acceptability of home blood sampling for people living with HIV

## PRIMARY OBJECTIVES

- To determine the limit of: detection, sensitivity and specificity of HIV RNA viral load quantification from finger prick whole blood collected in EDTA microcontainers vs. standard venepuncture 6ml EDTA tubes
- To assess the feasibility and acceptability of small volume testing for home sampling for routine blood tests for routine HIV monitoring



## SECONDARY OBJECTIVES

- To assess concordance between liver function test parameters and creatinine collected from 600µl finger prick compared to standard venepuncture 6ml EDTA tubes

**PHASE 1 Recruitment inclusion criteria:**

- Convenience sample of people living with HIV-1 attending clinic for routine blood tests as part of their HIV care
- >18 years
- Able to provide written consent

73 participants with **UNDETECTABLE**  
HIV-1 Viral Load: <50 copies/mL



73 participants with **DETECTABLE**  
HIV-1 Viral Load: >50 copies/mL

Each participant has paired blood samples taken on the same day:

**Routine venepuncture:**

HIV-1 VL, LFTs, creatinine (2x 6 ml tubes: EDTA, SST)



**TINIES finger prick tests:**

HIV-1 VL (2x EDTA micro-containers)  
LFTs, creatinine (1 x SST microcontainer) –optional

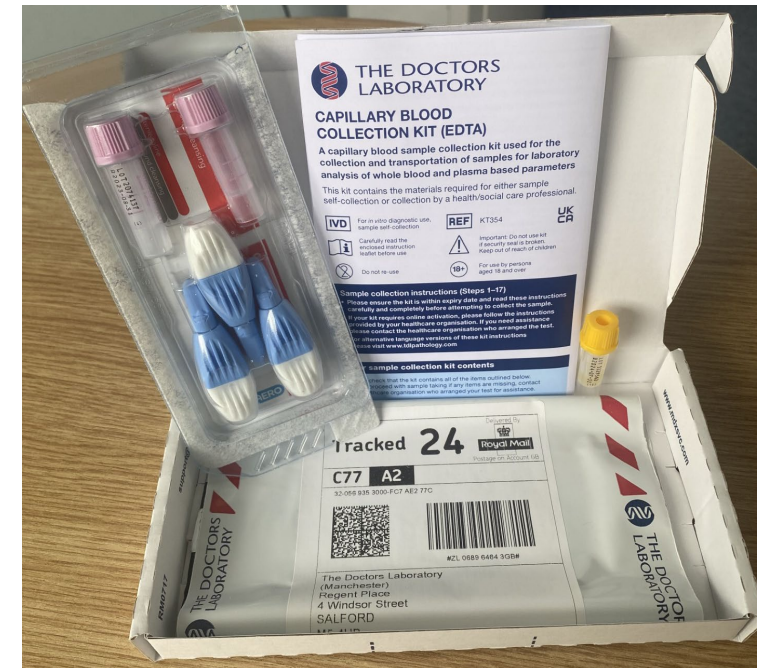
NB TINIES samples are diluted and undetectable  
is reported as <90 copies/mL

## PHASE 2 Recruitment inclusion criteria:

- Convenience sample of people living with HIV-1 attending clinic for routine blood tests as part of their HIV care
- >18 years
- Able to provide written consent

## PHASE 2

Subset of 50 participants sent TINIES test kit to use in home environment, with written or online response survey



**TINIES EDTA - purple**

- 2x EDTA bottles (over 500µl) make one HIV-1 RNA Viral Load test

**TINIES SST – yellow (optional sample)**

- 2x SST bottles (over 600µl) for testing for LFTs and creatinine

**Routine venepuncture:**

- HIV-1 VL (6ml EDTA tube)
- LFTs and creatinine (6 ml SST tube)





## RESULTS

- 113 people living with HIV recruited between 1<sup>st</sup> April 2023 – 25<sup>th</sup> March 2024
- Results from 15 people living with HIV showed HIV VL >50 copies/mL (**detectable**)
- Results from 19 people living with HIV had unusable results
- Results from 79 people living with HIV showed HIV VL <50 copies/mL (**undetectable**) were compared to their matched TINIES samples:

### VENOUS SAMPLES:

79 samples reported as <50 copies/mL



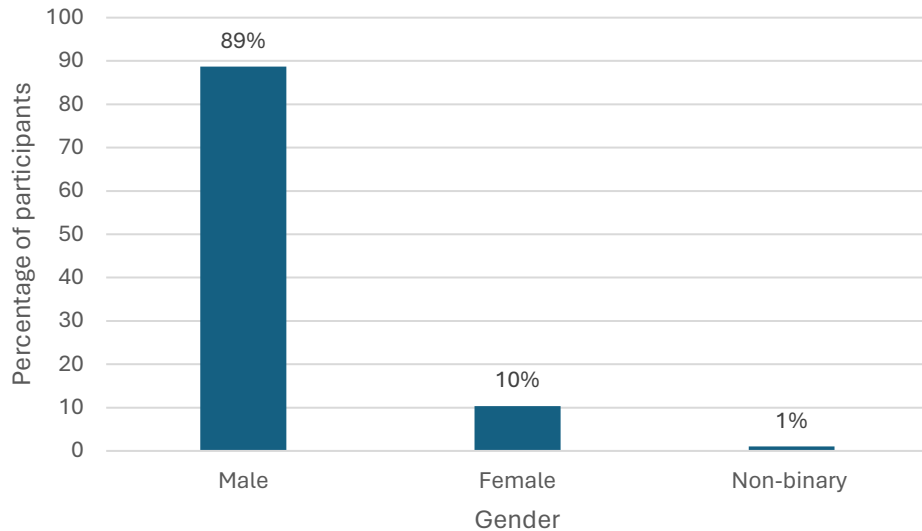
### MATCHED TINIES SAMPLES:

79 samples reported as <50 copies/mL

# RESULTS

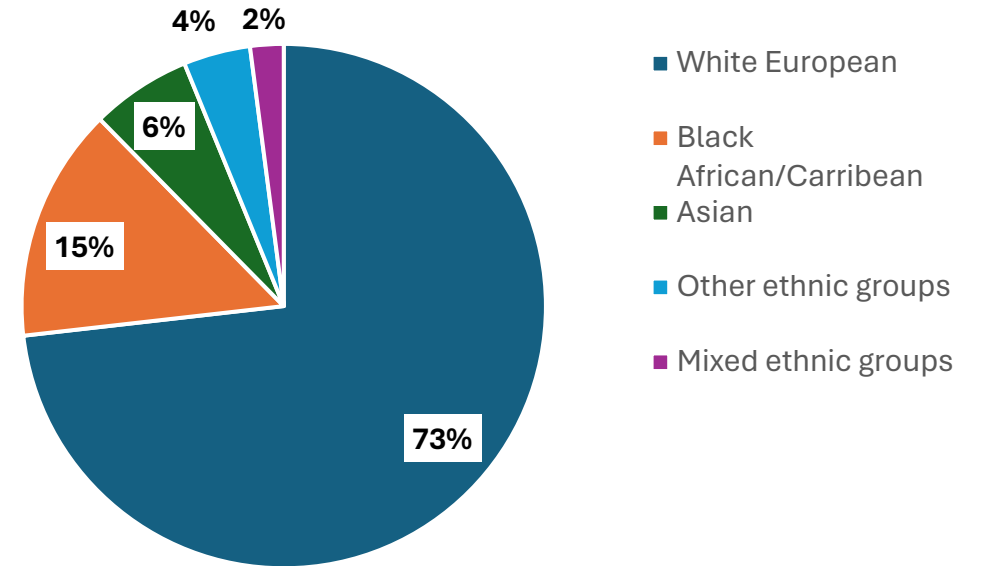
**Undetectable** participants recruited 1<sup>st</sup> April 2023 – 25<sup>th</sup> March 2024:

Gender subgroups within the HIV **undetectable** cohort



Gender	Male	Female
Aim	80%	20%

Ethnic subgroups within the HIV **undetectable** cohort



Ethnic Group	White European	Black African and Caribbean	All other ethnic groups
Aim	70%	20%	10%

## REASONS FOR FAILURE

- Samples from 19 participants (17%) were not usable due to laboratory processing and logistical issues:
- Insufficient sample
  - Fasting
  - Hard skin on the fingers
  - Cold hands
  - Patient requesting to stop or not consenting to additional finger needle punctures to collect sample
- Laboratory machinery failure
- Laboratory closure over bank holidays

## CONCLUSIONS

- Results from Phase 1 of the study showed 100% concordance between venous blood and TINIES samples amongst virally suppressed people living with HIV
- The reasons for the 17% sample failure rate are being investigated.
- Recruitment of participants with detectable HIV viral load is ongoing
- Patient acceptability will be investigated further in Phase 2

## ACKNOWLEDGMENTS

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- James Mason – Clinical Research Assistant
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- Dr Laura Waters – HIV lead and recruitment
- Dr Philippa Matthews – HBV recruitment
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