

Towards elimination of HIV amongst gay and bisexual men in the United Kingdom

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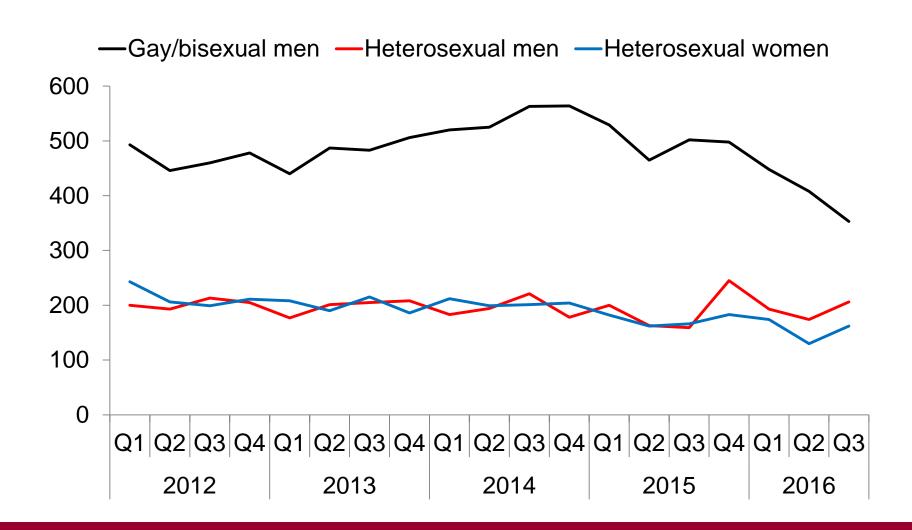


Investigation into reports of a drop in new diagnoses: Background & Context

- WHO refers to HIV elimination as less than one new case per 1,000 population
- HIV incidence rates in gay and bisexual men and other men who have sex with men living in the UK are estimated at 5-10/1,000 overall and 30+/1,000 among STI attendees with a bacterial infection
- The UK has open access, high quality and free and STI & HIV testing and care
- Testing guidelines and new testing modalities (eg home sampling)
- Long history of health promotion programmes with relatively high uptake of condoms
- PROUD trial began in late 2015, internet Prep since mid 2016
- Reports of decreases in new diagnoses in some London clinics in late 2016
- We used national and local trends in new HIV diagnoses, HIV testing and uptake of ART to investigate the likely cause of the observed drop in new diagnoses

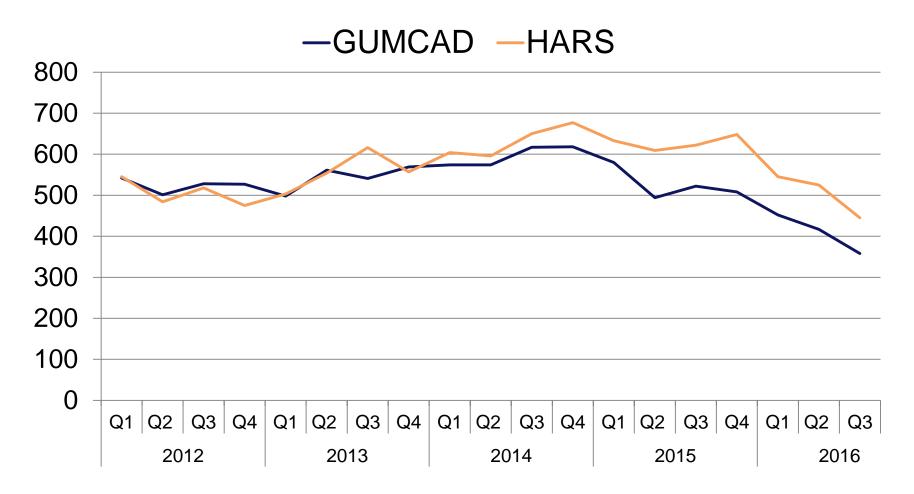


New HIV diagnoses among adults attending sexual health services





New HIV diagnoses among gay men in England



Note: There has been a year on year increase in the median CD4 cell count at diagnosis over this period indicating earlier diagnosis



Methodology 1

Information on new diagnoses and testing among all gay men attending sexual health clinics (GUMCAD)

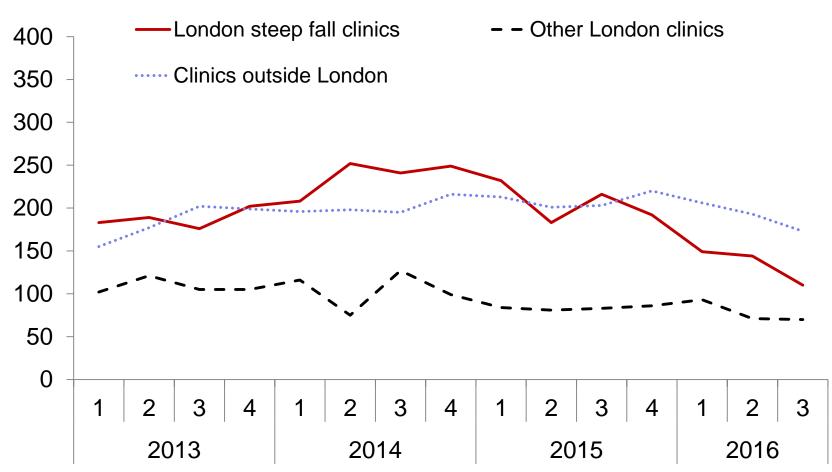
Clinic Strata

- Clinic with a 'significant' or steep fall: Clinics with >20% decrease in HIV diagnoses between Oct 2014-Sep 2015 and Oct 2015-Sep2016, and over 40 diagnoses during this period.
- Dean St, Mortimer Market, Homerton, St Mary, Guy and St Thomas
- Other London clinics and clinic in other parts of England

Testing data on men attending for HIV test at the same clinic in the last 2 years (repeat testers) and those who had a new test in last 2 years



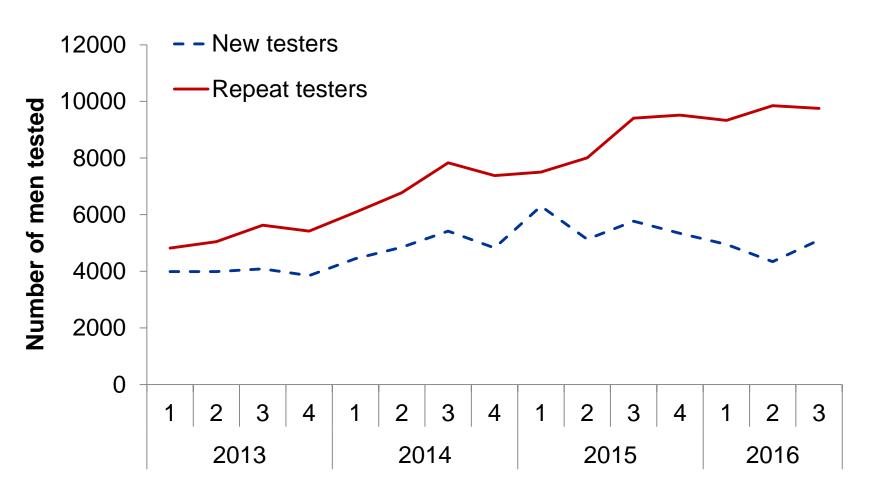
New HIV diagnoses among gay men attending sexual health clinics England



Steep fall definition: Clinics with >20% decrease in HIV diagnoses between Oct 2014-Sep 2015 and Oct 2015-Sep2016, and over 40 diagnoses during this period.



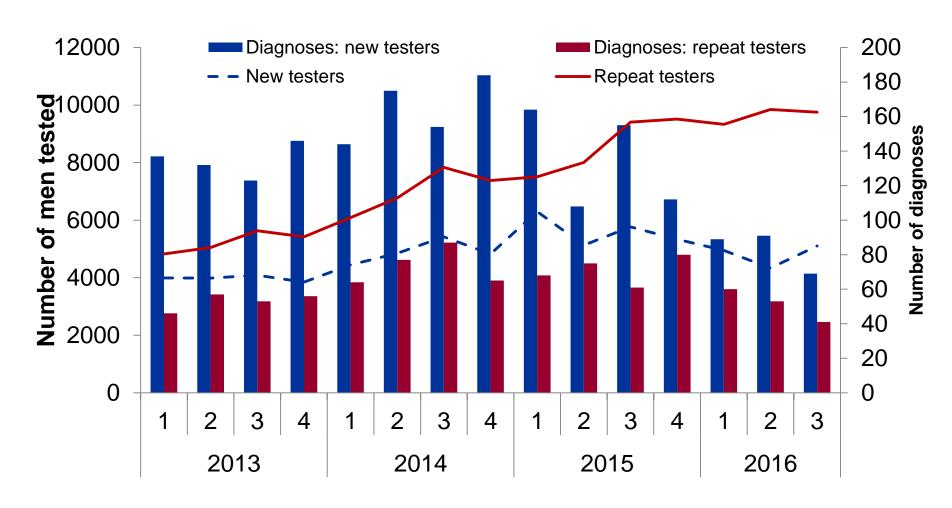
HIV tests among gay men attending London Steep Fall clinics by frequency of HIV testing



Steep Fall: Clinics with >20% decrease in HIV diagnoses between Oct 2014-Sep 2015 and Oct 2015-Sep2016, and over 40 diagnoses during this period.

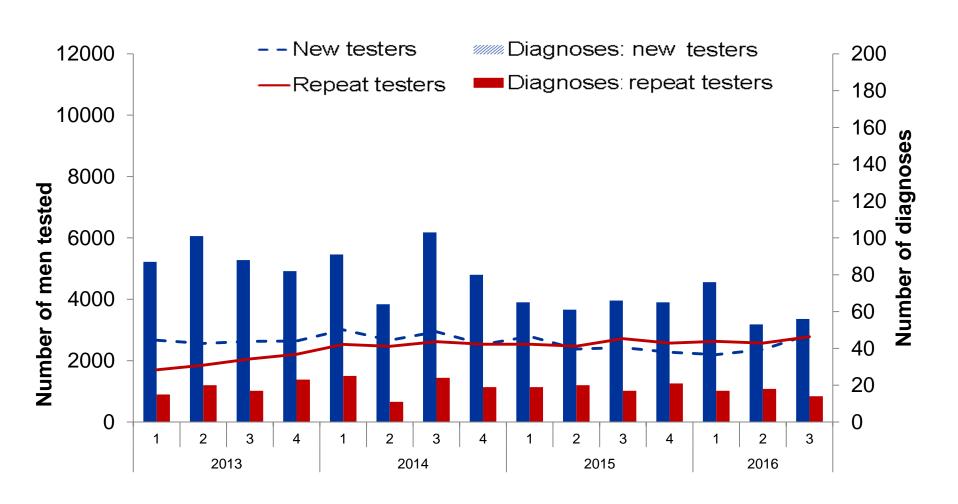


HIV tests and new diagnoses among gay men attending London Steep Fall clinics (N=5)



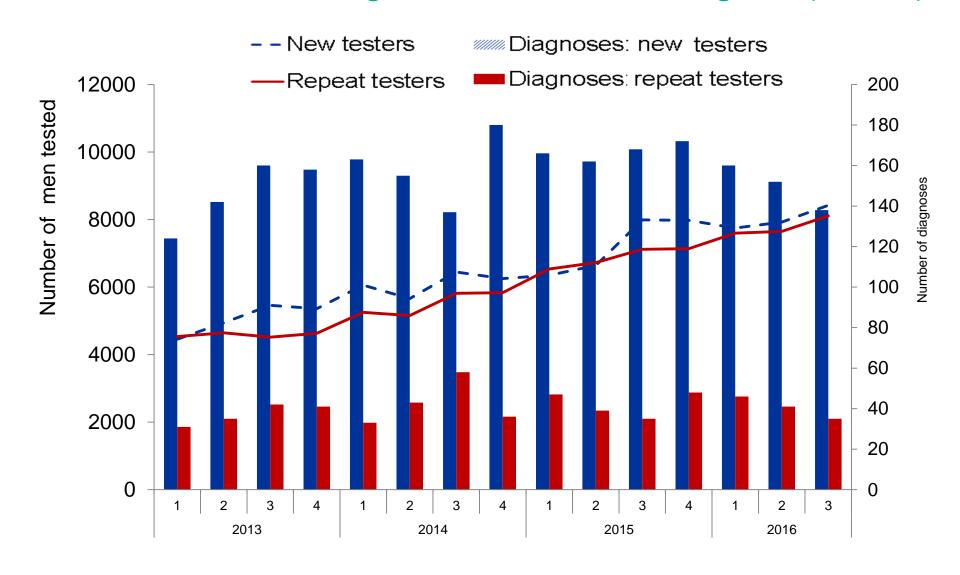


HIV tests and new diagnoses among gay men attending other London clinics (N=30)



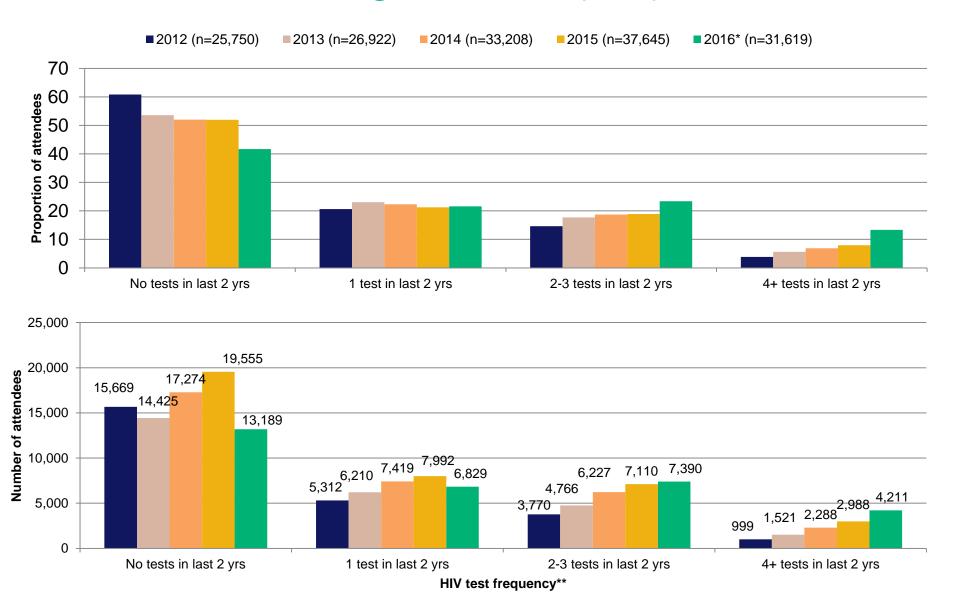


HIV tests and new diagnoses among gay men attending clinics in the rest of England (N=190)





Frequency of HIV testing among men attending SF clinics (n=5)





Methodology 2

Information on men diagnosed with HIV from diagnosis and follow up data when attending HIV services (HARS)

 Median days from diagnosis to ART on available data (about 80%) is used as a proxy for Treatment as Prevention (TasP)

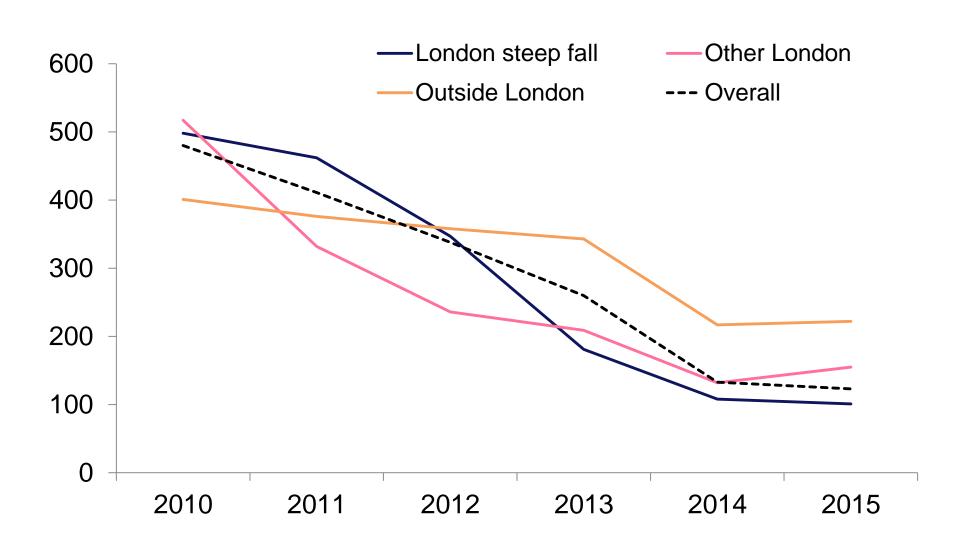
Transmissible Viral Load

- Only persons that are undiagnosed or had a viral load >200 copies/mL at date last seen for HIV care can potentially transmit HIV
- Persons at high risk of HIV acquisition
- HIV negative men with a documented STI in previous year was defined as High risk

Transmissibility Ratio: Total men with transmissible VL/ Total number of high risk men

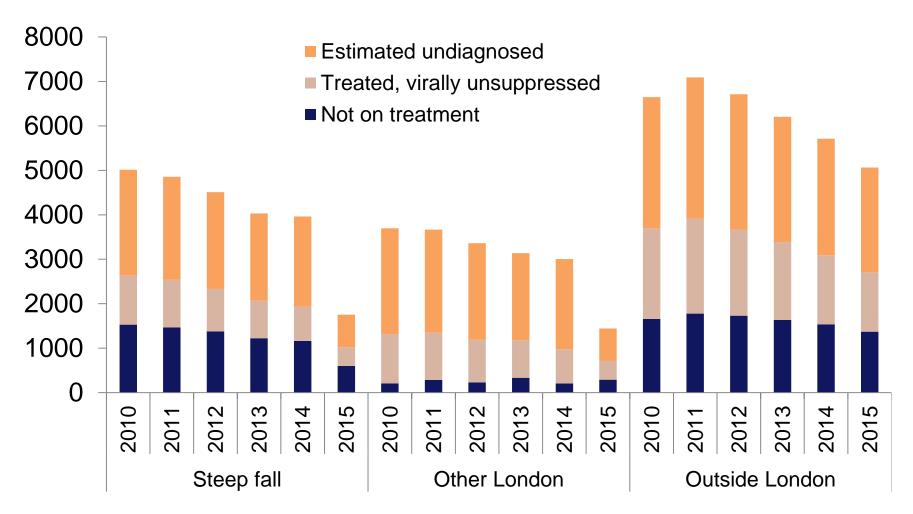


Median days from HIV diagnosis to ART initiation among gay men in England





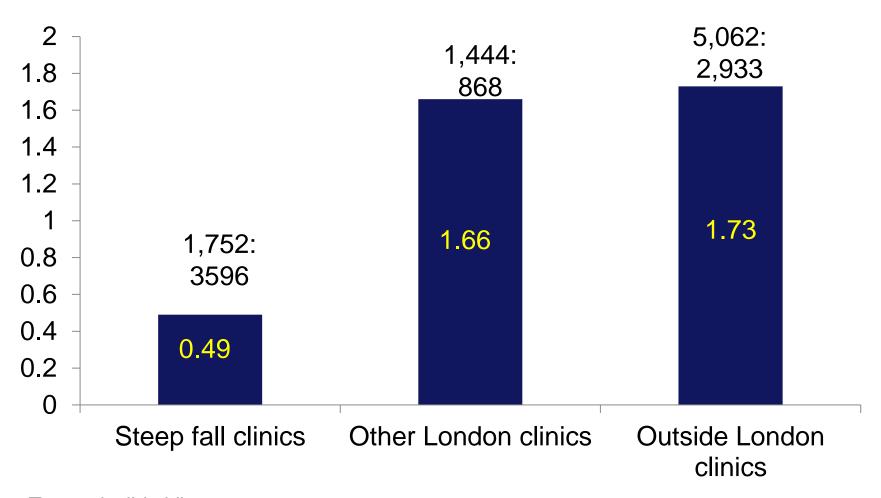
Transmissibility: Estimated number of gay men with viral load > 200 copies/mL by clinic strata



^{*}Estimated undiagnosed, diagnosed untreated and those treated with viral load >200 copies/mL



Transmissibility ratio by clinic, 2015



Transmissible VL: Estimated undiagnosed, diagnosed untreated or on ART with viral load >200 copies/mL

High risk men: HIV negative with a history of an STI in previous year



Summary

- 1. We are witnessing and recording an ecological experiment of the impact of combination prevention on HIV incidence
- A substantial fall in new HIV diagnoses fell was observed at five London clinics in the last quarter of 2016 compared to the previous year with smaller declines observed at other London clinics, and elsewhere in England.
- 3. The rise in median CD4 count at diagnosis indicates fall in diagnosis is likely to reflect decrease in incidence
- 4. We need to consolidate scaling up of testing and early ART across all parts of the country for all groups at greatest risk of HIV
- 5. Prep use likely to have also contributed to the fall in new diagnoses but its use has been relatively low to date But that is about to change....



Protecting and improving the nation's health



Microbicides for women

Abdool Karim Q, Science 2010

Treatment for

prevention

Donnell D, Lancet 2010 Cohen M, NEJM 2011



Auvert B. PloS Med 2005 Gray R. Lancet 2007 Bailey R. Lancet 2007

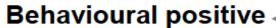




Grosskurth H, Lancet 2000

Female Condoms





HIV PREVENTION TOOL-KIT





HIV Counselling and Testing



Coates T, Lancet 2000





Scheckter M, 2002



Rerks-Ngarm S, NEJM 2009

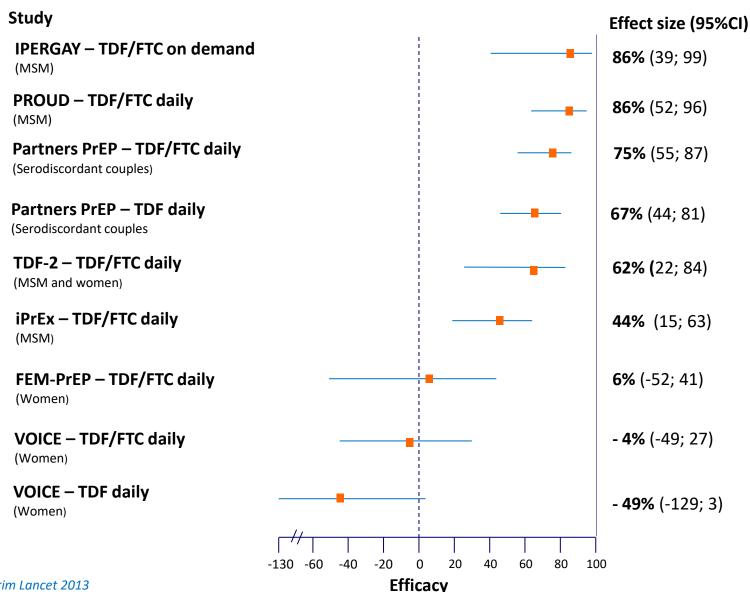
Behavioural Intervention

- Abstinence
- Be Faithful



Note: PMTCT, Screening transfusions, Harm reduction, Universal precautions, etc. have not been included - this is focused on reducing sexual transmission

Summary results of oral PrEP studies



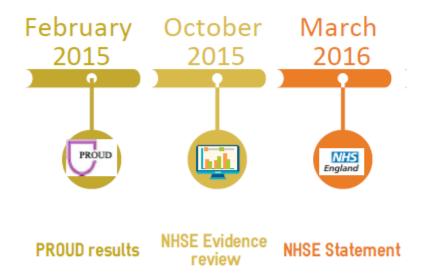


PROUD results

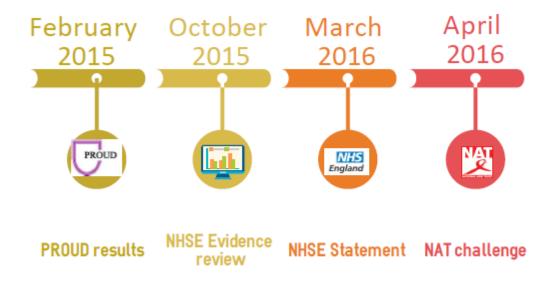
http://www.proud.mrc.ac.uk/study_results

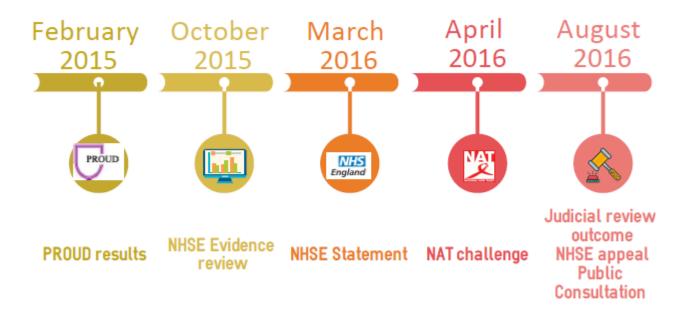


https://www.engage.england.nhs.uk/consultation/specialised-services/user_uploads/f03x06-evidnc-rev.pdf



https://www.england.nhs.uk/2016/03/prep/

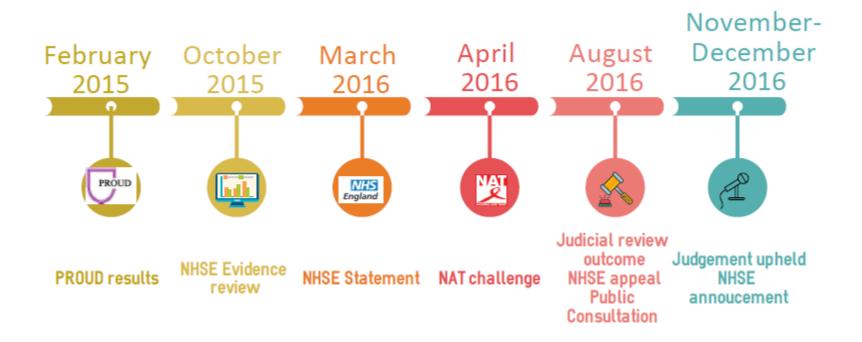




https://www.judiciary.gov.uk/wp-content/uploads/2016/08/nat-v-nhs-judgment.pdf

https://www.england.nhs.uk/2016/08/august-update-on-the-commissioning-and-provision-of-pre-exposure-prophylaxis-prep-for-hiv-prevention/

https://www.engage.england.nhs.uk/consultation/specialised-services



https://www.england.nhs.uk/2016/11/update-on-prep/https://www.england.nhs.uk/2016/12/hiv-prevention-pregramme/







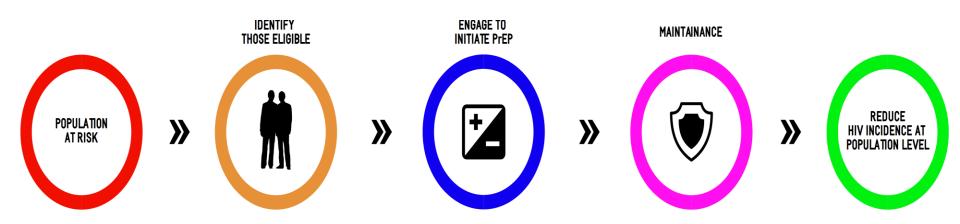
Address key outstanding questions

- 1) Proportion eligible for PrEP?
- 2) How to identify, engage and maintain all people eligible for PrEP?
- 3) Proportion accepting offer of PrEP?
- 4) Proportions choosing daily or intermittent dosing?
- 5) Duration of PrEP use?
- 6) Impact on HIV incidence?
- 7) Impact on STI incidence?

Primary objective

To measure PrEP-eligibility, PrEP-uptake, duration of PrEP-eligibility and duration of PrEP-use among Genitourinary Medicine (GUM) clinic attendees

PrEP prevention care continuum



Portman M et al. BASHH 2016

Secondary objectives

Secondary

- 1. To investigate incident HIV infections in trial participants
- 2. To measure change in HIV diagnoses and incidence rate in those at high HIV risk
- 3. To measure change in bacterial STI diagnoses and incidence in those at high HIV risk
- 4. To measure the PrEP "prevention care continuum" by clinic throughput and in different regions

Inclusion criteria

Key principles of the IMPACT trial inclusion criteria:

Include all persons at high risk of HIV:

- 1. Higher risk sexual behaviour
- 2. HIV positive partner
- 3. Partner of unknown status and at high risk of HIV

Inclusion Criteria

- 1 Cis- and transgender MSM and trans women
 - a) HIV negative test in previous year
 - b) Report condomless sex in the previous 3 months
 - c) Affirm likelihood of CSI in the next 3 months
- 2 HIV negative partner of an HIV positive person
 - a) HIV positive partner not known to be virally suppressed
 - b) CSI anticipated before treatment of HIV positive partner takes effect
- 3 HIV negative person

Clinically assessed and considered to be at similar risk of HIV acquisition as those with a serodiscordant partner who is not known to be virally suppressed

Pre-enrolment

Pre-enrolment Enrolment

- Baseline tests
- 3-month PrEP prescription (daily or EBD)
- GUMCAD codes

Pre-enrolment

Enrolment

- Baseline tests
- 3-month PrEP prescription (daily or EBD)
- GUMCAD codes

Follow up

- HIV/STI tests according to standard of care
- Hepatitis C test according to routine practice
- Renal review
- Combination prevention
- Safety check
- PrEP prescription
- GUMCAD codes

Monitoring



GUMCAD SHHAPT codes and variables

- PrEP Eligibility Variable
- PrEP Outcome SHHAPT Code
- PrEP Regimen Variable (how has PrEP been recommended or prescribed?)
- PrEP Dose Variable (since last visit, how was it taken?)
- PrEP Adherence Variable (what proportion of risk episodes covered?)

Site selection



GUMCAD reporting services



Geographical spread

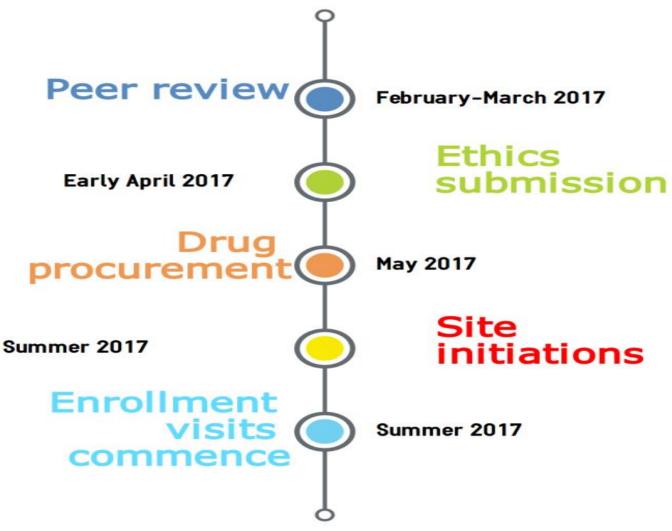


Variety by size, throughput and population



Participant spaces allocated by site and population group

Proposed trial timeline



Proposed trial timeline

Trial development workstreams:

Governance

Protocol and peer review

Trial and site logistics

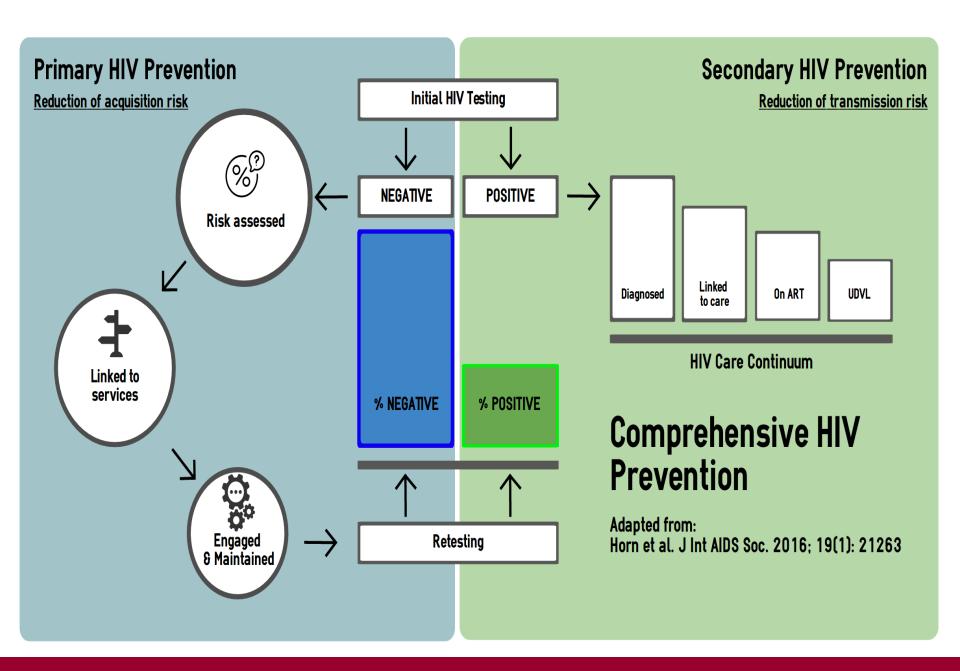
NIHR

Structural development (e.g. GUMCAD)

Drug procurement, delivery and dispensing

Communications

Community and clinical engagement



Acknowledgements

PHE colleagues, in particular: Noel Gill, John Saunders, Nigel Field, KohJun Ong, Martina Furegato, Andre Charlett, Sarika Desai, Kevin Fenton, Victoria Hall, Nalini Iyengar, Anthony Nardone, Luis Guerra, Gwenda Hughes, Hamish Mohammed, Dana Ogaz, Nicky Connor, Alison Brown, Cuong Chau, Peter Kirwan, Zheng Yin and the rest of the HARS and GUMCAD teams

Sheena McCormack, Ann Sullivan, NIHR

SSAT team, Task and Finish Group, Community Engagement Group



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Thank you