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

Drs Valerie Delpech and Monica Desai
On behalf of the HIV & STI team at Colindale
Public Health England
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 (e.g., home sampling).
- Long history of health promotion programmes with relatively high uptake of condoms.
- 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

- Gay/bisexual men
- Heterosexual men
- Heterosexual women

Current HIV trends in England
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
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-Sep 2016, 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-Sep 2016, 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-Sep 2016, 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)

<table>
<thead>
<tr>
<th>HIV test frequency**</th>
<th>2012 (n=25,750)</th>
<th>2013 (n=26,922)</th>
<th>2014 (n=33,208)</th>
<th>2015 (n=37,645)</th>
<th>2016* (n=31,619)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No tests in last 2 yrs</td>
<td>15,669</td>
<td>14,425</td>
<td>13,189</td>
<td>12,319</td>
<td>11,259</td>
</tr>
<tr>
<td>1 test in last 2 yrs</td>
<td>6,210</td>
<td>7,419</td>
<td>7,992</td>
<td>6,829</td>
<td>6,227</td>
</tr>
<tr>
<td>2-3 tests in last 2 yrs</td>
<td>5,312</td>
<td>6,227</td>
<td>7,110</td>
<td>7,390</td>
<td>999</td>
</tr>
<tr>
<td>4+ tests in last 2 yrs</td>
<td>999</td>
<td>1,521</td>
<td>2,288</td>
<td>4,211</td>
<td>2,988</td>
</tr>
</tbody>
</table>

Proportion of attendees

Number of attendees

HIV trends in England
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

Graph showing the trend in median days from HIV diagnosis to ART initiation among gay men in England from 2010 to 2015. The graph compares London steep fall, Other London, and Outside London, as well as an overall trend. The median days decrease over the years, with London steep fall showing the steepest decline.
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

2. 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....
Microbicides for women
Abdool Karim Q, Science 2010

Treatment for prevention
Donnell D, Lancet 2010
Cohen M, NEJM 2011

Male circumcision
Auvert B, PloS Med 2005
Gray R, Lancet 2007
Bailey R, Lancet 2007

Treatment of STIs
Grosskurth H, Lancet 2000

Female Condoms

Male Condoms

HIV Counselling and Testing
Coates T, Lancet 2000

HIV PREVENTION TOOL-KIT

Vaccines

- Abstinence
- Be Faithful

Behavioural Intervention

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Effect size (95%CI)</th>
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<tbody>
<tr>
<td>IPERGAY – TDF/FTC on demand</td>
<td>86% (39; 99)</td>
</tr>
<tr>
<td>(MSM)</td>
<td></td>
</tr>
<tr>
<td>PROUD – TDF/FTC daily</td>
<td>86% (52; 96)</td>
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<tr>
<td>(MSM)</td>
<td></td>
</tr>
<tr>
<td>Partners PrEP – TDF/FTC daily</td>
<td>75% (55; 87)</td>
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<tr>
<td>(Serodiscordant couples)</td>
<td></td>
</tr>
<tr>
<td>Partners PrEP – TDF daily</td>
<td>67% (44; 81)</td>
</tr>
<tr>
<td>(Serodiscordant couples)</td>
<td></td>
</tr>
<tr>
<td>TDF-2 – TDF/FTC daily</td>
<td>62% (22; 84)</td>
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<tr>
<td>(MSM and women)</td>
<td></td>
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<tr>
<td>iPrEx – TDF/FTC daily</td>
<td>44% (15; 63)</td>
</tr>
<tr>
<td>(MSM)</td>
<td></td>
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<tr>
<td>FEM-PrEP – TDF/FTC daily</td>
<td>6% (-52; 41)</td>
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<tr>
<td>(Women)</td>
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<tr>
<td>VOICE – TDF/FTC daily</td>
<td>- 4% (-49; 27)</td>
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<tr>
<td>(Women)</td>
<td></td>
</tr>
<tr>
<td>VOICE – TDF daily</td>
<td>- 49% (-129; 3)</td>
</tr>
<tr>
<td>(Women)</td>
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</tbody>
</table>
UK PrEP timeline

February 2015

PROUD results

http://www.proud.mrc.ac.uk/study_results
UK PrEP timeline

February 2015

PROUD results

October 2015

NHSE Evidence review

UK PrEP timeline

February 2015: PROUD results
October 2015: NHSE Evidence review
March 2016: NHSE Statement

https://www.england.nhs.uk/2016/03/prep/
UK PrEP timeline

- February 2015: PROUD results
- October 2015: NHSE Evidence review
- March 2016: NHSE Statement
- April 2016: NAT challenge
UK PrEP timeline

February 2015
PROUD results

October 2015
NHSE Evidence review

March 2016
NHSE Statement

April 2016
NAT challenge

August 2016
Judicial review outcome
NHSE appeal
Public Consultation

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

February 2015  PROUD results
October 2015  NHSE Evidence review
March 2016  NHSE Statement
April 2016  NAT challenge
August 2016  Judicial review outcome
November-December 2016  NHSE appeal Public Consultation

https://www.england.nhs.uk/2016/12/hiv-prevention-pregramme/
PrEP IMPACT Trial

- £10m
- 10,000
- 3 years
PrEP prevention care continuum

Portman M et al. BASHH 2016
## Secondary objectives

<table>
<thead>
<tr>
<th>Secondary</th>
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<tbody>
<tr>
<td>1. To investigate incident HIV infections in trial participants</td>
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<tr>
<td>2. To measure change in HIV diagnoses and incidence rate in those at high HIV risk</td>
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<tr>
<td>3. To measure change in bacterial STI diagnoses and incidence in those at high HIV risk</td>
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<tr>
<td>4. To measure the PrEP “prevention care continuum” by clinic throughput and in different regions</td>
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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

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

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
<table>
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<th>Pre-enrolment</th>
<th>Enrolment</th>
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Pre-enrolment

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- 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

- **Peer review**: February–March 2017
- **Drug procurement**: May 2017
- **Ethics submission**: Summer 2017
- **Enrollment visits commence**: Summer 2017
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
Thank you