The PROUD study
Creating desire for PrEP in the UK

Creating Desire for Microbicides 13-14May2014
Overview

- Context
  - Health care providers
  - Commissioners

- PROUD pilot study design

- Baseline results
  - Who is enrolling?
  - Sexual risk

- Public and Participant Involvement
The UK clinic/public health network

• ~250 sexual health clinics reporting to 2 public health agencies
  ➢ 27 participating in enhanced surveillance
• Walk-in service for HIV and STI screening
• HIV outpatients (not all; but all prescribe PEP)
• ~320 local authorities commission sexual health; National commissioning for HIV
• Standards set by two professional organisations
  ➢ British HIV Association
  ➢ British Association for Sexual Health and HIV
The UK epidemic

- Gradual increase in HIV in MSM since 2000
  - ~85% diagnosed in sexual health clinics
  - ~80% acquired in UK
- Fall in heterosexual HIV but rise in numbers acquired in UK
Preparing the ground

- iPrEx reports November 2010
- BASHH/BHIVA request Position Statement to enable HCW to discuss PrEP
- PrEP eGroup launched April 2011
- Proven biological efficacy of PrEP, but ‘real world’ effectiveness unknown

PROUD designed to assess this
- integrated into existing risk reduction package
- must not undermine condoms
PRAIRED Pilot Study

PRe-exposure Option for reducing HIV in the UK: an open-label randomisation to immediate or Deferred daily Truvada for HIV negative gay men
PROUD Pilot

Born male, reporting past, and intended, $C_0 \text{Al}$
Willing to take a pill now or in 12M

Randomize 500 HIV negative eligible individuals
(exclude if on treatment for hepB)

Risk reduction includes
Truvada **NOW**

Risk reduction includes
Truvada **in 12M**

Follow **3 monthly** for up to 24 months

Main endpoints: recruitment and retention
Progress

- January 2012: funding for PROUD rejected
- March 2012: Public Health England/MRC Clinical Trials Unit/Gilead support Pilot
- BASHH/ASTDA debate, June 2012: supports limiting PrEP access to clinical research setting
- FDA approve Truvada as PrEP July 2012
Progress

- August 2012: Researchers meet with Commissioners
- August 2012: ethics review PROUD
- September-November 2013: HCW knowledge, attitudes and practices survey
Volunteers

Why take part?

The study will give us more information about how PrEP could be used to prevent new HIV infections amongst gay men. By taking part, you could reduce your own risk of catching HIV.

Our team will help and support you to be healthy.

You can take part in the study if you:

- Are HIV negative
- Are 18 or older
- Have had anal sex without a condom in the last three months.
- Are likely to do this again in the next three months.
- Can visit the clinic for blood tests every three months.
- Are likely to do this again in the next three months.
### Key demographics at baseline

<table>
<thead>
<tr>
<th>Category</th>
<th>Number (N=439-443)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>35.5</td>
<td>IQR: 29.4-42.3</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>349</td>
<td>80%</td>
</tr>
<tr>
<td>Black</td>
<td>14</td>
<td>4%</td>
</tr>
<tr>
<td>S Asian</td>
<td>27</td>
<td>6%</td>
</tr>
<tr>
<td>Other</td>
<td>48</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Maximum education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University degree or above</td>
<td>258</td>
<td>59%</td>
</tr>
<tr>
<td>A-levels/equivalent</td>
<td>73</td>
<td>17%</td>
</tr>
<tr>
<td>No qualifications</td>
<td>11</td>
<td>3%</td>
</tr>
<tr>
<td>Other</td>
<td>97</td>
<td>23%</td>
</tr>
<tr>
<td><strong>Enrolled as partners</strong></td>
<td>17 (+1 triplet)</td>
<td></td>
</tr>
</tbody>
</table>
## Sexual risk at baseline

<table>
<thead>
<tr>
<th>Sexual partners</th>
<th>Median</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>10</td>
<td>4-20</td>
</tr>
<tr>
<td>Condomless receptive anal sex</td>
<td>2</td>
<td>1-5</td>
</tr>
<tr>
<td>Condomless insertive anal sex</td>
<td>3</td>
<td>1-6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Partnerships</th>
<th>Number (N=440)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In ongoing partnership</td>
<td>206</td>
<td>47%</td>
</tr>
<tr>
<td>Living with partner</td>
<td>138</td>
<td>31%</td>
</tr>
</tbody>
</table>
## Reasons for no condoms

<table>
<thead>
<tr>
<th>Reasons for no condom</th>
<th>Frequency of responses (N=1362)</th>
<th>Percentage of cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>It’s much more enjoyable without a condom</td>
<td>289</td>
<td>66%</td>
</tr>
<tr>
<td>I don’t like using condoms</td>
<td>222</td>
<td>51%</td>
</tr>
<tr>
<td>He doesn’t like using condoms</td>
<td>143</td>
<td>33%</td>
</tr>
<tr>
<td>Condoms weren’t discussed</td>
<td>116</td>
<td>27%</td>
</tr>
<tr>
<td>Under the influence of drugs</td>
<td>102</td>
<td>23%</td>
</tr>
<tr>
<td>I don’t consider myself at risk of HIV</td>
<td>98</td>
<td>22%</td>
</tr>
<tr>
<td>Under the influence of alcohol</td>
<td>94</td>
<td>22%</td>
</tr>
<tr>
<td>I was only dipping</td>
<td>81</td>
<td>19%</td>
</tr>
<tr>
<td>We don’t use condoms with each other, but do with other partners</td>
<td>74</td>
<td>17%</td>
</tr>
<tr>
<td>Other less frequent reasons</td>
<td>143</td>
<td>33%</td>
</tr>
</tbody>
</table>
Partner serostatus at last anal sex

- +ve, on treatment: 27%
- +ve, not on treatment: 4%
- +ve, don't know treatment status: 2%
- Negative: 44%
- Don't know: 23%
## PEP use

<table>
<thead>
<tr>
<th>PEP use</th>
<th>Number (N=420)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least once in past 12 months</td>
<td>177</td>
<td>40%</td>
</tr>
<tr>
<td>&gt;once in past 12 months</td>
<td>87</td>
<td>21%</td>
</tr>
</tbody>
</table>
Sexually transmitted infections

### History of STI in past 12 months at baseline

- Rectal Gonorrhoea: 26%
- Oral Gonorrhoea: 24%
- Urethral Gonorrhoea: 23%
- Rectal Chlamydia: 23%
- Urethral Chlamydia: 15%
- Oral Chlamydia: 13%
- Syphilis: 10%
- Genital warts: 9%
- Genital herpes: 4%
- LGV: 2%
- Hepatitis C: 0.5%
- Hepatitis B: 0.3%


STDs in Men who have sex with men http://www.cdc.gov/std/stats10/msm.htm
Recreational drug use

- 322/434 (74%) report use of recreational drugs in past 12 months

<table>
<thead>
<tr>
<th>Drug</th>
<th>Frequency of reports (N=957)</th>
<th>Percentage of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poppers (amyl nitrate)</td>
<td>213</td>
<td>67%</td>
</tr>
<tr>
<td>Viagra</td>
<td>182</td>
<td>57%</td>
</tr>
<tr>
<td>Mephadrone</td>
<td>158</td>
<td>49%</td>
</tr>
<tr>
<td>GHB (liquid ecstasy)</td>
<td>136</td>
<td>43%</td>
</tr>
<tr>
<td>Cannabis</td>
<td>102</td>
<td>32%</td>
</tr>
<tr>
<td>Cocaine (coke)</td>
<td>113</td>
<td>35%</td>
</tr>
<tr>
<td>Ecstasy</td>
<td>84</td>
<td>26%</td>
</tr>
<tr>
<td>Crystal meth (methamphetamine)</td>
<td>78</td>
<td>24%</td>
</tr>
</tbody>
</table>

Public Involvement

- Community Engagement Group
  - To oversee launch
  - Designed promotional material and spread the word about PROUD

- Expanded meeting to address slow recruitment June 2013
  - Highlighted lack of awareness
  - Joint Community Statement supporting PrEP
  - Articles to raise awareness and promote PROUD
  - Bannered on internet dating sites
56 Dean Street — Chelsea and Westminster Hospital
www.chelwest.nhs.uk/services/hiv-sexual. /56 dean street/56 dean street

Your friendly convenient central London sexual health and HIV clinic based in Soho.

56 Dean Street offers convenient appointments for STD (STI) tests.
5.0 ★★★★★ 14 Google reviews · Write a review · Google+ page

35 Dean St, London W1D 6AQ
020 3315 6699
Participant Involvement

- November 2013
  - Supported need for real-life effectiveness and proceeding to full scale trial
  - Did not like ‘stereotypical images’
- March 2014
  - Endorsed daily dosing, and Truvada
    - Convenient, known efficacy, known safety
    - Willing to consider half a pill a day
  - Minority willing to test long acting injectables and rectal microbicides
    - All against placebo-controlled
    - Accept deferred option, but preference Truvada control
Summary

• Creating desire takes time – time to spread the knowledge
• Science has delivered new technology with terrible economic timing, and room for mixed messages
• Lucky in UK to have established and joined-up clinic and community network
• Gathering evidence – quantitative and qualitative – is the only way to counteract concerns and prejudice, and ensure the key messages are understood
• Dissemination of the evidence will need to be broad, deep and loud, and above all consistent
Acknowledgements (1)

Study participants

MRC CTU at UCL (also financial support)
David Dolling, David Dunn, Mitzy Gafos, Gemma Wood, Liz Brodnicki, Yolanda Collaco-Moraes, Sarah Banbury, Brendan Mauger, Yinka Sowunmi, Christina Chung, Sheena McCormack

HIV & STI Dept, PHE (also financial support)
Anthony Nardone, Noel Gill, Sarika Desai, GUMCAD team, HIV team

Clinics and Clinical Research Network (also financial support)
Vanessa Apea, John Saunders (Barts Health NHS Trust), Nicola Mackie (St Mary’s Hospital), Alan McOwan (56 Dean Street), Amanda Clarke, Martin Fisher (Claude Nichol Centre), Christine Bowman (Sheffield Teaching Hospitals NHS Foundation Trust), Charles Lacey (York Hospitals NHS Foundation Trust), Gabriel Schembri (Manchester Centre for Sexual Health), Richard Gilson (The Mortimer Market Centre), Ann Sullivan (John Hunter Clinic for Sexual Health), Iain Reeves (Homerton University Hospital NHS Foundation Trust), Michael Brady, Jake Bayley (Kings College Hospital NHS Foundation Trust), Julie Fox (Guy’s and St Thomas’s NHS Foundation Trust), Steve Taylor, David White (Heart of England NHS Foundation Trust), Saye Khoo (University of Liverpool)
Acknowledgements (2)

Trial Steering Committee

**Independent members:** Mike Adler (Co-Chair), Gus Cairns (Co-Chair), Dan Clutterbuck, Rob Cookson, Claire Foreman, Stephen Nicholson, Tariq Sadiq, Matthew Williams

**Investigator members:** Brian Gazzard, Noel Gill, Anne Johnson, Sheena McCormack, Andrew Phillips

Community Engagement Group

Alan McOwan (Lead), Yusef Azad (NAT), Anthony Bains, Gus Cairns (NAM), Rob Cookson (LGF), Tom Doyle (Mesmac), Mitzy Gafos (MRC CTU at UCL), Justin Harbottle (THT), Matthew Hodson (GMFA), Cary James (THT), Ben McClelland (THT), Sheena McCormack (MRC CTU at UCL), Francesa McNeil (PHE), Roger Pebody (NAM), Annabelle South (MRC CTU at UCL)

Gilead (drug, and grant for diagnostics including PK)

Jim Rooney, Rich Clarke, Matt Bosse, Murad Ruf

**Academia:** Will Nutland (LSHTM)

**Social media:** Darren Clapich (Grindr), Simon Johnson (Gaydar)

**Press:** David Rowlands (Baseline), Robert Fieldhouse (Baseline), Chris O’Connor (Baseline), Patrick Cash (QX)