<table>
<thead>
<tr>
<th>Speaker Name</th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monica Desai</td>
<td>Speaker fees from Janssen</td>
</tr>
</tbody>
</table>

Date | April 2016
Baseline Predictors of HIV Infection in the no-PrEP Group in the PROUD Trial

Monica Desai on behalf of the PROUD team

22nd Annual Conference of the British HIV Association
Manchester April 2016
What is PrEP?

- Antiretroviral given to HIV negative persons to prevent HIV infection

- Truvada = tenofovir + emtricitabine

- PrEP prevents HIV

- WHO recommends for populations with >3% incidence
The PROUD trial

- 544 men who have sex with men (MSM) in the UK
- Immediate vs deferred PrEP
- Inclusion criteria:
  a) In 3 months prior to enrolment
  b) Anticipate condomless anal intercourse again in the next 3 months
- HIV test every 3 months
- Primary endpoint: compared HIV incidence between arms

**Kaplan-Meier failure estimates**

<table>
<thead>
<tr>
<th>Months in study</th>
<th>Immediate</th>
<th>Deferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>260</td>
<td>246</td>
</tr>
<tr>
<td>6</td>
<td>256</td>
<td>234</td>
</tr>
<tr>
<td>9</td>
<td>252</td>
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<td>12</td>
<td>243</td>
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<td>15</td>
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<td>18</td>
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<td>21</td>
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<td>24</td>
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<td>30</td>
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<td>25</td>
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<tr>
<td>33</td>
<td>9</td>
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</table>

Percentage HIV-1 Infected

Number at risk

- Immediate
- Deferred
Aim

To identify characteristics of men who are at the highest risk of HIV infection and would most benefit from PrEP
HIV negative cohort

544 MSM reporting UAI last/next 90 days

275 assigned to IMMEDIATE

269 assigned to DEFERRED
HIV negative cohort

- 544 MSM reporting UAI last/next 90 days
- 275 assigned to IMMEDIATE
- 269 assigned to DEFERRED

Exclusions:
- 1 HIV +ve at baseline
- 2 co-enrollers
- 13 no HIV test after baseline
HIV negative cohort

**544** MSM reporting UAI last/next 90 days

- **275** assigned to IMMEDIATE
- **269** assigned to DEFERRED
- **253** included in analysis

**Exclusions:**
- 1 HIV +ve at baseline
- 2 co-enrollers
- 13 no HIV test after baseline
HIV incidence

- Time to HIV diagnosis
- 253 participants (220 person years)
- 20 HIV infections
- Incidence rate = 9.1 per 100PY
HIV incidence (90% CI) by baseline characteristics

**Rectal STI**
- **Yes**: 162 (7)
- **No**: 81 (12)

**URAI partners**
- **0**: 31 (1)
- **1**: 76 (2)
- **2-4**: 76 (8)
- **5-9**: 33 (4)
- **10+**: 27 (4)

**Chemsex**
- **Yes**: 134 (8)
- **No**: 110 (10)

**PEP use**
- **Yes**: 152 (11)
- **No**: 85 (8)

**Relationship**
- **Cohabiting**: 66 (6)
- **Non-cohabiting**: 46 (2)
- **Single**: 138 (12)

---

A: Reported in previous 12 months
B: Reported in previous 90 days
HIV incidence (90% CI) by baseline characteristics

- **Rectal STI**:
  - No: 162 (7)
  - Yes: 81 (12)
  - P-value: 0.01

- **URAI partners**:  
  - 0: 31 (1)
  - 1: 76 (2)
  - 2-4: 76 (8)
  - 5-9: 33 (4)
  - 10+: 27 (4)
  - P-value: 0.02

- **Chemsex**:  
  - No: 134 (8)
  - Yes: 110 (10)
  - P-value: 0.39

- **PEP use**:  
  - No: 152 (11)
  - Yes: 85 (8)
  - P-value: 0.57

- **Relationship**:
  - Cohabiting: 66 (6)
  - Non-cohabiting: 46 (2)
  - Single: 138 (12)
  - P-value: 0.63

A: Reported in previous 12 months
B: Reported in previous 90 days

MRC CTU @ UCL
HIV incidence (90% CI) by baseline characteristics

- Rectal STI:  
  - No: 81 (12)  
  - Yes: 162 (7)  
  - P-value: 0.01

- URAI partners:  
  - 0: 31 (1)  
  - 1: 76 (2)  
  - 2-4: 76 (8)  
  - 5-9: 33 (4)  
  - 10+: 27 (4)  
  - P-value: 0.02

- Chemsex:  
  - No: 134 (8)  
  - Yes: 110 (10)  
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- PEP use:  
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- Relationship:  
  - Cohabiting: 66 (6)  
  - Non-cohabiting: 46 (2)  
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A: Reported in previous 12 months  
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HIV incidence (90% CI) by baseline characteristics

- **Rectal STI**^A: No: 162 (7), Yes: 81 (12), P-value: 0.01
- **URAI partners**^B: 0: 31 (1), 1: 76 (2), 2-4: 76 (8), 5-9: 33 (4), 10+: 27 (4), P-value: 0.02
- **Chemsex**^B: No: 134 (8), Yes: 110 (10), P-value: 0.39
- **PEP use**^A: No: 152 (11), Yes: 85 (8), P-value: 0.57
- **Relationship**: Cohabiting: 66 (6), Non-cohabiting: 46 (2), Single: 138 (12), P-value: 0.63

A: Reported in previous 12 months
B: Reported in previous 90 days

MRC CTU @ UCL
### Who is most at risk?

**Rank:**

1. Rectal STI  17.4
2. 2+ URAI   13.9
3. PEP        10.9
4. Chemsex    10.4

<table>
<thead>
<tr>
<th>Predictors of high risk</th>
<th>Number of seroconversion for each risk factor (total no. of seroconversions)</th>
<th>Total PY of follow up</th>
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<td>17.4</td>
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### Who is most at risk?

**Exclude with STI**

#### Rank:
1. 2+ URAI  |  9.5  
2. PEP       |  9.4  
3. Chemsex   |  7.1  

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<td>13.6</td>
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### Who is most at risk?

#### Rank:

1. PEP  5.1
2. Chemsex  3.5

---

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<tr>
<td>PEP usage</td>
<td>1 (19)</td>
<td>152.0</td>
<td>12.5</td>
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Exclude with 2+ URAI partners
Who is most at risk?

### Ranking:

1. Chemsex 4.9

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<td>1 (19)</td>
<td>152.0</td>
<td>12.5</td>
</tr>
<tr>
<td>Chemsex</td>
<td>1 (20)</td>
<td>172.3</td>
<td>11.6</td>
</tr>
</tbody>
</table>

Exclude with PEP usage
Conclusions

• All risk factors identified men who were above the level of “substantial risk”, defined by WHO

• Highest risk – bacterial rectal STI or 2+ anal sex partners with no condom

• GMC guidance states that it is a doctor’s duty to explain the risk of HIV to patients and provide them with information on all options to reduce their risk. This has to include PrEP.
Acknowledgements

Study participants

MRC CTU at UCL
Sarah Banbury, Liz Brodnicki, Christina Chung, Yolanda Collaco-Moraes, Monica Desai, David Dolling, David Dunn, Mitzy Gafos, Sajad Khan, Brendan Mauger, Sheena McCormack, Yinka Sowunmi, Ellen White, Gemma Wood

HIV & STI Dept, PHE
Monica Desai, Sarika Desai, Noel Gill, Anthony Nardone, GUMCAD team, HIV team

Clinics
Vanessa Apea, John Saunders, Mags Portman (Barts Health NHS Trust), Christine Bowman (Sheffield Teaching Hospitals NHS Foundation Trust), Michael Brady (Kings College Hospital NHS Foundation Trust), Martin Fisher, Amanda Clarke (Claude Nichol Centre), Julie Fox (Guy’s and St Thomas’s NHS Foundation Trust), Richard Gilson (The Mortimer Market Centre), Charles Lacey (York Hospitals NHS Foundation Trust), Nicola Mackie (St Mary’s Hospital), Alan McOwan, Simone Antonucci (56 Dean Street), Iain Reeves (Homerton University Hospital NHS Foundation Trust), Gabriel Schembri (Manchester Centre for Sexual Health), Ann Sullivan (John Hunter Clinic for Sexual Health), Steve Taylor, David White (Heart of England NHS Foundation Trust)
See updated BHIVA/BASHH position statement, practical guide and infographics
Supplementary slides
## HIV incidence by risk factor

<table>
<thead>
<tr>
<th></th>
<th>HIV incidence</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rectal STI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>17.4</td>
<td>10.8, 28.0</td>
</tr>
<tr>
<td>No</td>
<td>5.0</td>
<td>2.68, 9.29</td>
</tr>
<tr>
<td><strong>Number of partners</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>3.43</td>
<td>0.66, 17.8</td>
</tr>
<tr>
<td>1</td>
<td>3.01</td>
<td>0.94, 9.62</td>
</tr>
<tr>
<td>2-4</td>
<td>12.8</td>
<td>7.17, 22.9</td>
</tr>
<tr>
<td>5-9</td>
<td>13.7</td>
<td>6.01, 31.1</td>
</tr>
<tr>
<td>10+</td>
<td>17.2</td>
<td>7.55, 39.1</td>
</tr>
<tr>
<td><strong>PEP</strong></td>
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<td></td>
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<tr>
<td>Yes</td>
<td>10.9</td>
<td>6.07, 19.4</td>
</tr>
<tr>
<td>No</td>
<td>8.37</td>
<td>5.09, 13.7</td>
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<tr>
<td><strong>Chemsex</strong></td>
<td></td>
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<tr>
<td>Yes</td>
<td>10.4</td>
<td>6.19, 17.5</td>
</tr>
<tr>
<td>No</td>
<td>6.90</td>
<td>3.86, 12.3</td>
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</table>
### Number of partners and rectal STI

<table>
<thead>
<tr>
<th>Number of partners</th>
<th>Rectal STI (N, %)</th>
<th>Odds of rectal STI in patients with 10+ partners is 7.3 times greater than among those with 0 partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>5 (17%)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>16 (22%)</td>
<td></td>
</tr>
<tr>
<td>2-4</td>
<td>28 (37%)</td>
<td></td>
</tr>
<tr>
<td>5-9</td>
<td>15 (47%)</td>
<td></td>
</tr>
<tr>
<td>10+</td>
<td>16 (60%)</td>
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</table>
### HIV incidence (90% CI) by baseline characteristics

![Graph showing HIV incidence by baseline characteristics](image)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Yes</th>
<th>No</th>
<th>N (infections)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rectal STI</strong>&lt;sup&gt;A&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td><strong>URAI partners</strong>&lt;sup&gt;B&lt;/sup&gt;</td>
<td></td>
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<td></td>
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<td></td>
<td>0.57</td>
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<tr>
<td><strong>Relationship</strong></td>
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</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
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<td>0.26</td>
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A: Reported in previous 12 months  
B: Reported in previous 90 days
Who is most at risk?

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<tr>
<th>Predictors of high risk</th>
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