P200 Attitudes and beliefs towards early ART initiation in MSM with primary HIV infection
Parsons, V*; Porter, K; Gilson, R; Hart, G (London, UK)

P201 The suspected unexpected and serious adverse events of antiretroviral drugs used as HIV prophylaxis in HIV uninfected persons
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P202 Acceptability of PrEP among HIV negative Portuguese men who have sex with men that attended 2014 Lisbon pride fair
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P203 Attitudes of serodiscordant couples towards antiretroviral-based HIV prevention strategies in Kenya; a qualitative study
Fowler, N*; Arkell, P; Abouyannis, M; James, C; Roberts, L (Birmingham, UK)

P204 Safety, tolerability and effectiveness of HIV non-occupational prophylaxis in Taiwan
Li, H*; Cheng, Y; Yang, C (Taipei City, Taiwan)

*Indicates presenting author.
Two Years of Truvada for Pre-Exposure Prophylaxis Utilization in the United States

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Background

• Truvada® (TVD) was approved in July 2012 by the US FDA for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in high-risk adults.
• This study explores the characteristics of US PrEP users and their prescribers over 2 years ending in March 2014.

Materials and Methods

• A previously described algorithm was used to identify TVD for PrEP1 by excluding users for HIV treatment, post-exposure prophylaxis, and off-label treatment of chronic hepatitis B.
• National electronic patient level data from ~ 55% of all U.S. retail pharmacies that dispensed TVD between January 1, 2012 and March 31, 2014 were collected.
• De-identified patient-level data including prescription refill data, medical claims, and patient demographics were analyzed via logistic regression to estimate the odds of change by year.

Results

• A total of 3253 unique individuals who started TVD for PrEP between January 1, 2012 and March 31, 2014 were included in this analysis.
• Women comprised 42.0% of PrEP users.
• Overall, new TVD for PrEP starts per quarter increased from 293 in Q1 2012 to 472 in Q1 2014 (Figure 1).
• Comparing the quarters ending March 31, 2013 and March 31, 2014, the number of new starts among females dropped from 44.5% to 22.9%.
• The proportion of males under 25 was lower than that of women, 17.2% (95% CI: 15.3 - 19.3).
• Although mean age (SD) was 38.1 +/- 11.9 years and the proportion varied slightly over time,
• Males were significantly older (39.3 +/- 11.6) than females (36.4 +/- 12.3).
• The proportion of males under 25 was 7.4% (95% CI: 6.3 - 8.7); significantly lower than that of women. 17.2% (95% CI: 15.3 - 19.3).

Figure 1. Quarterly TVD for PrEP Starts by Gender

• Using a multivariable logistic model, we compared uninfected subjects in this dataset receiving TVD for PrEP to HIV+ patients receiving TVD-based treatment regimens.
• PrEP users were:
  – In 2013,
    • Uninfected females were 1.4 times more likely to start TVD for PrEP than HIV+ females started on a TVD-based regimen (95% CI: 1.2 – 1.5, p <0.001);
    • Uninfected subjects younger than 25 years of age were 1.5 times more likely to be started on TVD for PrEP than HIV+ patients younger than 25 years of age started on a TVD-based regimen (95% CI: 1.3 – 1.8, p<0.001).
  – In Q1 2014,
    • The probability of females starting TVD for PrEP declined to 0.5 times more likely than HIV+ females started on a TVD-based regimen (95% CI: 0.4 – 0.7, p<0.001).

• Uninfected subjects younger than 25 years of age had the same probability as HIV+ patients younger than 25 years of age started on a TVD-based regimen (95% CI: 1.2 – 2.4, p<0.001).

Figure 3. TVD for PrEP Prescriptions by Specialty

• The population of TVD for PrEP users in the US nationally appears to be shifting demographically.
• The overall proportion of female PrEP users decreased between Q1 2012 and Q1 2014.
  – When compared to HIV+ patients on a TVD-based regimen, PrEP users were more likely to be female in 2013 but less likely in Q1 2014.
• A small proportion of PrEP users were under 25 years of age consistently across each quarter.
  – When compared to HIV+ patients on a TVD-based regimen, PrEP users were more likely to be under 25 years of age both in 2013 and Q1 2014.
• PrEP prescriptions continues to be initiated mostly by non infectious disease physicians.
• More community-level data on usage will be helpful in informing local efforts to integrate Truvada for PrEP in HIV prevention messaging and services.

Conclusions

• There were no significant differences in the characteristics of PrEP users by gender or age.
• The population of TVD for PrEP users in the US nationally appears to be shifting demographically.
• The overall proportion of female PrEP users decreased between Q1 2012 and Q1 2014.
  – When compared to HIV+ patients on a TVD-based regimen, PrEP users were more likely to be female in 2013 but less likely in Q1 2014.
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1. Mera-Giler RM et. al. Poster H-663a. 53rd ICAAC, Denver, CO September 2013
Attitudes and beliefs towards early ART initiation in MSM with primary HIV infection

V Parsons, K Porter, R Gilson and G Hart
University College London, UK

Background
ART initiation in primary HIV infection (PHI) could reduce risk of transmission to sexual partners at a time of high viraemia, although health benefit for the individual remains unknown. We examined attitudes to early ART and associated beliefs in men who have sex with men (MSM) with PHI.

Methods
Semi-structured face-to-face in-depth interviews were conducted with 13 MSM aged ≥16 years. Men were recruited from a central London HIV clinic and interviewed within 12 months of date of estimated HIV seroconversion. Audio recordings of interviews were transcribed verbatim, imported into NVIVO and analysed thematically using the Framework approach developed by NatCen.

Results
Median age of participants was 33 years (range 22-47), majority were of white British ethnicity (n=8), educated to university level (n=11), and were not on ART at the time of interview (n=10).

Expectations around starting ART were diverse, with some men assuming they would be prescribed ART immediately upon diagnosis. Deferral until CD4<350 came as a surprise and seemed counterintuitive to these men when put into the context of treating other diseases. As expected, the role of the doctor in the decision making process was central, with many men stating they will start when told to by their clinician.

Key themes around early ART emerging from the interviews are presented in figure 1, with descriptions and quotes from the participants.

Conclusions
Factors involved in the decision to start ART early are complex and involve balancing the perceived benefits and barriers. Uncertainty over evidence of individual health benefits and long term free provision of ART in the NHS, in conjunction with fear of side effects, toxicities and resistance were barriers to starting ART early. By contrast early ART was seen as a way of improving future health, reducing stigma, facilitating disclosure, and limit the consequences of infection until a cure is found.

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The suspected unexpected and serious adverse events of antiretroviral treatment used as HIV prophylaxis in HIV uninfected persons.

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1. Hospital for Infectious Diseases, HIV Out-Patient Clinic, Warsaw, Poland 2. Medical University of Warsaw, Department for Adult’s Infectious Diseases, Warsaw, Poland

Background
- With increased usage of antiretroviral drugs (ARVs) in HIV uninfected persons proper reporting on suspected unexpected serious adverse reactions (SUSARs) and continued insight into serious adverse events (SAEs) is needed for adequate information on ARVs safety in such populations.

Methods
- We have evaluated medical documentation of persons receiving ARVs after non-occupationally HIV exposure (nPEP) during five concomitant years (2009-2013).
- SAEs and SUSARs were evaluated by two HIV physicians and defined according to international standards.
- In statistical analyses Cox proportional hazard models were used to identify independent predictors of developing SAE.
- Only the first SAE was included in these analyses.

Results
- In total 375 persons received nPEP.
- The most common reason was needle stick (43%) followed by unprotected sexual intercourse (37%), rape (30%) and first aid (10%).
- In 84 (22%) cases the source patient was either known to be HIV positive or within a high risk group (active injecting drug user).
- In total 170 SAEs were reported, 139 persons had only one SAE and majority developed it within first two weeks.
- The most frequent first SAEs were:
  - gastrointestinal disorders (21%)
  - followed by general symptoms (9%)
  - hypersensitivity reactions (1.3%)
  - CNS symptoms (1.5%).
- The remaining events were laboratory abnormalities of liver and kidney function, haematological disorders, other and unknown, each contributing to less than 1% of all patients.
- Eight (2.1%) patients have developed a SUSAR:
  - bradycardia
  - vivid dreams
  - lymphadenopathy of the neck
  - increased platelet count
  - swelling and pain of large joints
  - swelling of lower limbs
  - peripheral edema
  - loss of concentration
- In multivariate analyses only age was independent predictor of developing SAE (HR 1.34; 95% CI: 1.03-1.72; p=0.02) Table 1.

Conclusions
- In our observation SAEs in reaction to nPEP were frequent yet usually mild events, mostly occurring in first two weeks and rarely causing discontinuation.
- The only significant factor increasing the risk of SAE was age.
- SUSARs were both rare and rather insignificant.
- More insight into this important area is required in order to ascertain proper pharmacovigilance of ARVs usage in HIV uninfected persons.

Acknowledgments: the study has been sponsored by unlimited grant received from Research Development Foundation in Hospital for Infectious Diseases.

Table 1. Baseline characteristics.

<table>
<thead>
<tr>
<th></th>
<th>All n=375</th>
<th>ADEs reported n=159</th>
<th>No-ADEs n=216</th>
<th>p value</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td>34.5 (11.8)</td>
<td>31.7 (11.7)</td>
<td>25.5 (6.6)</td>
<td>0.02</td>
</tr>
<tr>
<td>PEP in days</td>
<td>25.5 (6.2)</td>
<td>25.2 (6.3)</td>
<td>26.3 (6.3)</td>
<td>0.69</td>
</tr>
<tr>
<td>Number (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male gender</td>
<td>206 (54.9)</td>
<td>74 (53.2)</td>
<td>132 (59.5)</td>
<td>0.67</td>
</tr>
<tr>
<td>Calendar year</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>139 (37.4)</td>
<td>50 (36.0)</td>
<td>89 (39.7)</td>
<td>0.20</td>
</tr>
<tr>
<td>2010</td>
<td>66 (18.2)</td>
<td>21 (15.7)</td>
<td>45 (21.0)</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>47 (12.4)</td>
<td>15 (11.8)</td>
<td>32 (14.9)</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>66 (17.6)</td>
<td>28 (20.2)</td>
<td>38 (17.6)</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>57 (15.3)</td>
<td>27 (19.4)</td>
<td>30 (13.2)</td>
<td></td>
</tr>
<tr>
<td>Type of exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual contact (MISM anal)</td>
<td>30 (8.1)</td>
<td>12 (8.6)</td>
<td>10 (8.5)</td>
<td>0.34</td>
</tr>
<tr>
<td>Sexual contact (MISM oral)</td>
<td>5 (1.3)</td>
<td>12 (8.6)</td>
<td>10 (8.5)</td>
<td>0.34</td>
</tr>
<tr>
<td>Sexual contact (vaginal)</td>
<td>28 (9.3)</td>
<td>13 (9.3)</td>
<td>15 (6.4)</td>
<td></td>
</tr>
<tr>
<td>Sexual contact (rap)</td>
<td>38 (10.4)</td>
<td>11 (7.9)</td>
<td>27 (12.4)</td>
<td></td>
</tr>
<tr>
<td>Physical contact</td>
<td>122 (32.6)</td>
<td>35 (25.2)</td>
<td>77 (35.6)</td>
<td></td>
</tr>
<tr>
<td>Needle stick</td>
<td>160 (42.7)</td>
<td>65 (46.8)</td>
<td>95 (44.2)</td>
<td></td>
</tr>
<tr>
<td>Source patient HIV-positive or active IDU</td>
<td>84 (22.4)</td>
<td>28 (20.2)</td>
<td>121 (56.2)</td>
<td>0.44</td>
</tr>
<tr>
<td>Use of three ARVs</td>
<td>156 (41.7)</td>
<td>58 (44.7)</td>
<td>98 (45.8)</td>
<td>0.30</td>
</tr>
<tr>
<td>Use of NNRTI</td>
<td>252 (67.3)</td>
<td>78 (58.3)</td>
<td>100 (46.3)</td>
<td>0.85</td>
</tr>
</tbody>
</table>

Odds ratios for serious adverse event

Adjusting for all above decreasing the odds of SAE increasing the odds of SAE
ACCEPTABILITY OF PrEP AMONG HIV NEGATIVE PORTUGUESE MEN WHO HAVE SEX WITH MEN THAT ATTENDED 2014 LISBON PRIDE FAIR

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BACKGROUND
According to [Prex 0, 1], oral HIV PrEP provides a high degree of protection against HIV infection, even for individuals who miss some daily doses. A study conducted between April 2011 and May 2013 found that 59.3% of their participants at baseline [1935 HIV negative MSM enrolled between April 2011 and May 2013] were eligible for PrEP, according to the 2014 USA PrEP guidelines. Oral HIV PrEP is not available in Europe and ECDC claims for more studies about PrEP acceptance and implementation to support policies among increasing and rolling out its use. Hence, the exploratory study about PrEP acceptability in MSM at Lisbon.

OBJECTIVES
Describe PrEP acceptability amongst HIV-negative Portuguese MSM.

METHODS
A street-based intercept survey, adapted from Mantei et al study [2], was applied to MSM attending the 2014 Lisbon Pride Fair. The survey included sociodemographic data, PrEP awareness and readiness to use it, probability of MSM’s social network to also use it, promptness to join PrEP-related studies, type of PrEP warranted and anal sex practice without using a condom in the last 6 months.

RESULTS
160 MSM were intercepted, 5 excluded because they report being HIV positive and 45 because they report other nationality and not living in Portugal.
110 HIV negative Portuguese MSM responded, with a median age of 33 and 84% of them identified themselves as gay.
A majority of MSM were unaware of PrEP (59%), those that were aware, had heard of it through CheckpointLX (31%), network (27%) or health professionals (20%).
66% were likely or very likely to participate in PrEP-related studies, 57% of MSM were likely or very likely to use PrEP if available and reported that some of not almost all of their social network will do it too (70%).
Type of PrEP preferred was oral, a pill a day (43%), followed by oral, intermittent intake (22%) and inject once a month (25%).
Overall, 41% of MSM had condomless anal sex practice in the last 6 months.

CONCLUSIONS
Awareness of PrEP amongst Portuguese MSM is limited.
Oral daily intake was the most acceptable via of administration.
According to USA PrEP guidelines, 41% MSM overall were eligible to use HIV PrEP.
Willingness to use PrEP is high and higher if MSM were to be enrolled in PrEP use studies, PrEP when available in Portugal, can be a powerful tool for HIV prevention in this key population.

INTRODUCTION

BACKGROUND

91,000 new HIV infections in Kenya (2011)
414 of these infections occur in serodiscordant couples
46% of married or cohabiting HIV-positive individuals do not consistently use a condom, indicating new methods of prevention are needed

The WHO has recommended two new prevention strategies
1. Treatment as Prevention (TasP)
   HIV-positive partner is initiated on antiretroviral therapy irrespective of CD4 or stage
2. Pre-Exposure Prophylaxis (PrEP)
   Non-HIV-negative partner is given daily oral antiretrovirals as a prophylaxis against HIV

Sample
Province, Kenya
of Nyando District, Nyanza

DESIGN
Qualitative study, semi-structured interviews of serodiscordant couples to PrEP or PrEP + TasP in Kenya

AIMS
1. To examine the attitudes of serodiscordant couples towards the use of TasP and/or PrEP as methods of HIV prevention
2. To gain an understanding of participants’ preferences for either TasP or PrEP

METHOD

DESEMIN: Qualitative study, semi-structured interviews

SETTINGS
Six clinics to four hospitals within the Muhimbi Constituency of Nyando District, Nyahururu

SAMPLE
Purposeful criterion sample of 81 individuals in a serodiscordant couple in a treatment or prevention setting

TABLE 1: Participant Characteristics

RESULTS

1. Attitudes Towards Treatment as Prevention (TasP)

TasP could improve the HIV-positive partner’s health
When you are HIV-positive and you are not on ARVs you are not healthy because if you are HIV-positive you had not accepted your status, so you have to go through all these counselling, somebody has to accept first” (F, 26, HIV +ve)

2. Attitudes Towards Pre-Exposure Prophylaxis (PrEP)

Men and women were concerned about future parenthood
"When you are HIV-positive and you are not on ARVs for a long time, it is not healthy because if you are HIV-positive you had not accepted your status, so you have to go through all these counselling, somebody has to accept first” (F, 35, HIV +ve)

3. Cross Cutting Themes

RISK COMPENSATION

A number of HIV-negative participants had HIV-based prevention methods because they wanted to stop using a condom, despite knowing that doctors would still recommend that use
"If a doctor said to wear a condom I will not use a condom, I will continue with the drugs without using a condom when making love” (M, 31, HIV –ve)

DOCTOR KNOWS BEST

Many participants indicated that they have a lot of faith in doctors and will follow their advice about treatment and prevention
"If the doctor told me to wear a condom I will not use it and continue with the drugs without using a condom when making love” (M, 31, HIV –ve)

TOWERS EXTRA PROTECTION

Additional protection was thought to be good particularly when condoms are in inconvenient or when they are trying to conceive
"Men don’t like condom, even if I want sometimes he doesn’t want a condom so I try to use something else or try to use another method” (F, 36, HIV –ve)

DISCUSSION

1. Treatment as Prevention (TasP)
   Most HIV-positive and negative partners disliked TasP, especially once TasP was introduced as an alternative

   KEY POINTS
   1. Likely adherence due to perceived benefit to both partners and unborn children
   2. A lack of status acceptance, pill burden and risk compensation were raised

   RECOMMENDATIONS
   1. TasP is likely to be acceptable to most in the region
   2. Thorough counselling is needed to address patient concerns as well as to emphasise the importance of continued condom use

2. Pre-Exposure Prophylaxis (PrEP)
   Most HIV-positive and non-positive partners disliked PrEP, especially once PrEP was introduced as an alternative

   KEY POINTS
   1. HIV-negative partners may have less motivation to hear the advantage and pill burden because they are healthy
   2. Thorough counselling is needed to address patient concerns

   RECOMMENDATIONS
   1. PrEP were to be introduced, public education and awareness campaigns, as well as patient counselling would be needed

LIMITATIONS

Small sample size
Social desirability bias
Only HIV-positive participants were ART naive
Influence of translator and cultural interpretation of questions

FUTURE RESEARCH

1. Whether TasP were to encourage status disclosure
2. How patient-partner and patient-doctor relationships may influence attitudes and adherence to ARV-based prevention

ACKNOWLEDGEMENTS

Many thanks to Sister Vincent, Austin Borrie and translators for their local support; (Anti-AIDS Teaching Trust and Mathew foundation, the participants in the study)
Safety, tolerability and effectiveness of HIV non-occupational prophylaxis (nPEP) in Taiwan

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No. P204

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Introduction
1. Increasing numbers of new human immunodeficiency virus infection (HIV) is an important issue of public health in Taiwan, especially sexually transmission.
2. Three drug based regimen had been conducted and recommended by formal guideline of U.S CDC since 2005 and was also accepted in Western countries.
3. Animal studies showed substantial attenuation in protective benefit when medication was administered 72 hours after SIV inoculation. The consequence was applied for non-occupational prophylaxis of high risk exposures in human beings.
4. Many clinical trials had demonstrated better tolerability and clinical efficacy of newer antiretroviral agents.

Objective
We aim to evaluate the safety, tolerability and effectiveness of HIV non-occupational prophylaxis (nPEP) in Taiwan.

Methods
1. Study design and duration: prospective observational study from March, 2011 to September 2014
2. Subjects: Persons who had high risk sexual exposure seeking for nPEP.
3. Individual consultation and information about basic personal characteristics were obtained by standard case record form.
4. HIV Rapid test and anti-HIV (EIA) were done concomitantly to evaluate baseline serologic status. Those who were tested positive of HIV infection at baseline were excluded. In addition, baseline HBV, HCV and RPR/TPPA were also checked.
5. Three-combined antiretroviral agents were given for total 28 days.
6. All the cases were followed with anti-HIV (EIA), RPR/TPPA, HBsAg, Anti-HBs and anti-HCV at 6 weeks, 12 weeks and 24 weeks after sexual exposure.

Results
1. During the study period, 298 cases sought for nPEP were enrolled while 2 cases were tested HIV positive before prophylaxis and were excluded.
2. Baseline characteristics demonstrated that the cases who sought for nPEP were composed by male (84.3%), education with college or higher (89.9%), unmarried (92.2%), 2-5 sex partners in the past 3 months (75.0%), Condom use below than 50% (58.1%). (Table 1)
3. Nearly ninety percent of cases received nPEP within 48 hours (Fig. 1) and 84.8 % of the cases had completed the course of prophylaxis.
4. TDF-based regimen had less adverse effect of nausea/vomiting but higher percentage of diarrhea.

Discussion
1. Our result demonstrated comparable completion rate of nPEP of AZT-based regimen versus TDF-based regimen. In addition, higher percentage of adverse effects among TDF-based regimen was also noted. The difference could probably attributed to the third anti-retroviral agent of nPEP since higher percentage of lopinavir/ritonavir were used in the TDF-based regimen.
2. Only one case were found to have HIV seroconversion at the 12th week follow up. However, the seroconversion could be attributed to his repeated high risk sexual behavior after nPEP without another course of prophylaxis.
3. Data collection bias of the adverse effect could also be the reason of the result.

1. Comparable tolerability of AZT-based regimen and TDF-based regimen was found according to our study.
2. Although this is an observational study, nPEP still demonstrated the efficacy in the prevention of HIV infection.