METHODS

METHODS FOR STUDY

Study began with a 6 week DOT lead-in phase
Participants were randomised: 1.1 to 24 weeks of one of three self-administered PrEP dosing strategies:
  • Daily: 1 tablet daily
  • Time-driven: 1 tablet twice a week plus 1 tab post-sex
  • Event-driven: 1 tablet 24-48 hours before and 1 tablet within 2 hours after sex
Bangkok was one of three study sites We contacted participants weekly to collect dates/times of PrEP use (using electronically) with the Wappli™ (pills dispensing device) and sex events Participants filled out a computer-assisted self-interview (CASI) about the study trial event and were followed until study closure and referred for post-care trial

METHODS FOR CURRENT ANALYSIS

Data from the study site only
Alcohol (AUDIT) score and substance use were assessed by computer-assisted self-interview
Use sex act as the unit of analysis
We used general estimating equations for clustered data to evaluate predictors associated with coverage
Coverage and adherence assessed without use of plasma concentrations

DEFINITION: COVERED EVENT
Coverage for all arms:
  21 pill taken in the 4 days before sex
  21 pill taken in the 24 hours after sex

RESULTS PRESENTED AT IAS 2015

Among Thai MSM: coverage (85%) and adherence (85%) and drug concentrations were high in the daily arm
Compared with the daily regimen (85%), the time-dosing regimen offered comparable high PrEP coverage (84%) for sex acts with fewer tablets required
In all arms, when a dose required for full coverage was missed, it was usually the post-sex dose
Adherence was greater in the daily arm (85%) compared with the time-dosing arm (79%) or event-driven arm (65%), but no statistically significant difference between daily and time-driven arms in adherence
Compared with the daily arm, the number of doses required for full adherence was reduced by 5% in the time-driven arm and by 80% in the event-driven arm (p<0.001)
2 seroconversions during the 6-week pre-randomization weekly DOT study phase, both occurred at week 4. No seroconversions during the self-administrated phase
Study results offer additional support for current CDC guidelines for daily PrEP dosing

PREDICTOR ANALYSIS

• Proportion of covered sex acts by those reporting stimulant use (coverage: 74%) was similar to those reporting other drug use (methamphetamine: 78% (p=0.80), but lower than those reporting no substance use (85%, p=0.04)
• In a multivariable model those factors associated with higher coverage included:
  • Age ≥25 years (adjusted odds ratio [aOR] 2.34, 95% CI 1.37–3.97, p=0.002)
  • Completion of college (aOR 1.74, 95% CI 1.04–2.92, p=0.003)
  • Moderate (AUDIT Score 7–12: aOR 1.75, 95% CI 1.15–2.66, p=0.01) to high levels (AUDIT Score ≥13: aOR 3.86, 95% CI 1.98–7.68, p<0.001) alcohol use
• In a multivariable model those factors associated with lower coverage included:
  • Higher number of reported sex events (13–40 over three months at baseline: aOR 0.57, 95% CI 0.32–1.00, p=0.05); 4 reported sex events as referent
  • Use of stimulant drugs (aOR 0.47, 95% CI 0.24–0.93, p=0.03)

METHODS FOR STUDY:

• Participant characteristics: Bangkok (N=178)

TABLE 1. Participant Characteristics, Bangkok

<table>
<thead>
<tr>
<th>Variable</th>
<th>% (N=178)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>31 (27.34)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 99%</td>
</tr>
<tr>
<td>Education</td>
<td>College completion 16%</td>
</tr>
<tr>
<td>Marital status</td>
<td>Married 97%</td>
</tr>
<tr>
<td>Occupation</td>
<td>Not employed 83%</td>
</tr>
<tr>
<td>Income</td>
<td>Not employed 6%</td>
</tr>
<tr>
<td>Unemployed</td>
<td>Student 9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
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</thead>
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<tr>
<td>Male vs. Female</td>
<td>3.86 (1.98–7.68)</td>
</tr>
<tr>
<td>College completion vs. no degree</td>
<td>0.57 (0.32–1.00)</td>
</tr>
<tr>
<td>0–4 reported sex events vs. 5–14</td>
<td>0.57 (0.32–1.00)</td>
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RESULTS

• Adherence was greater in the daily arm (85%) compared with the other arms in adherence
• Among Thai MSM, coverage (85%) and adherence (85%) and drug concentrations were high in the daily arm
• In all arms, when a dose required for full coverage was missed, it was usually the post-sex dose
• Adherence was greater in the daily arm (85%) compared with the time-dosing arm (79%) or event-driven arm (65%), but no statistically significant difference between daily and time-driven arms in adherence
• Compared with the daily arm, the number of doses required for full adherence was reduced by 5% in the time-driven arm and by 80% in the event-driven arm (p<0.001)
• 2 seroconversions during the 6-week pre-randomization weekly DOT study phase, both occurred at week 4. No seroconversions during the self-administrated phase
• Study results offer additional support for current CDC guidelines for daily PrEP dosing

TABLE 2: Univariate and Multivariate Analysis of Factors Associated with Higher Coverage of Sex Events, Bangkok HPTN 067/ADAPT Study (N=178)

<table>
<thead>
<tr>
<th>Variable</th>
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</table>

CONCLUSION

• Higher coverage of sex acts with PrEP was associated with a college education, and moderate to high (AUDIT score) baseline alcohol use, after adjusting for age
• Baseline use of stimulants and higher sexual frequency in the past 3 months was associated with lower adherence
• Regardless of substance use, the majority of Thai MSM/TGW followed the regimen dosing schedules to provide coverage of sexual exposures with PrEP

ACKNOWLEDGEMENTS

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