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The Dual Daily HIV and Syphilis Pre-Exposure Prophylaxis (DuDHS) Trial: Characteristics of Men who have Sex with Men Interested in Combined HIV and Syphilis PrEP.

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Background

- Conflict of Interest Disclosure: I have no conflicts of interest.
 - This research is partly funded by Gilead Sciences, Inc. and CIHR.
- Both syphilis and HIV disproportionately impact men who have sex with men (MSM).
- Proven efficacy of HIV pre-exposure prophylaxis (PrEP)
- Emerging evidence for syphilis PrEP with use of doxycycline
- DuDHS study is a pilot, **randomized, controlled trial (RCT)** to assess the **feasibility of dual daily syphilis and HIV PrEP** among MSM in Vancouver, BC.

Methods

- HIV-negative MSM with prior diagnosis of syphilis within the past 36 months were recruited (May 2018 to June 2019) from Vancouver sexual health clinics.
- Recruited via:
 1. Posters in clinic waiting rooms;
 2. Clinicians informing recently diagnosed syphilis clients.
- Participants received emtricitabine/tenofovir and were randomized (1:1) to either **immediate or deferred daily doxycycline (100mg)** for a 48-week follow-up.
- Recruitment success, baseline demographics, and sexual history are presented. Fisher's Exact/Chi-squared test and Kruskal Wallis test determined significant difference.

Results

Table 1. Characteristics of DuDHS trial participants at baseline.

| Variable | Overall n (%) | Immediate (N=26) n (%) | Deferred (N=26) n (%) | P-Value |
|-----------------------------|-----------------------|------------------------------|-----------------------------|----------------|
| Gender | | | | 1 |
| Male | 51 (98) | 25 (96) | 26 (100) | |
| Transgender | 1 (2) | 1 (4) | 0 | |
| Female | | | | |
| Ethnicity | | | | 0.590 |
| Caucasian | 24 (46) | 14 (54) | 10 (38) | |
| Latin American | 4 (8) | 2 (8) | 2 (8) | |
| Southeast Asian | 3 (6) | 1 (4) | 2 (8) | |
| Black | 2 (4) | 0 | 2 (8) | |
| Asian | 1 (2) | 1 (4) | 0 | |
| East Asian/Chinese | 1 (2) | 0 | 1 (4) | |
| South Asian | 1 (2) | 1 (4) | 0 | |
| Mulatto/mixed | 1 (2) | 1 (4) | 0 | |
| Post-secondary Education | | | | 0.609 |
| Yes | 33 (63) | 17 (65) | 16 (61) | |
| No | 4 (8) | 3 (6) | 1 (4) | |
| | Median (Q1-Q3) | Median (Q1-Q3) | Median (Q1-Q3) | P-Value |
| Age (years) | 34.5 (29-42.5) | 34.5 (30-43) | 34.5 (27-42) | 0.653 |

Missing responses removed. **Bolded text** indicates significant results at $P < 0.05$.

Study Recruitment/Enrolment Summary:

- 63 participants screened
- 52 participants enrolled
 - 31 (59.6%) clinician-referred
 - 11 (21.1%) self-referred
 - 1 (1.9%) peer-referred
 - 9 (17.3%) unknown referral

Table 2. Baseline sexually transmitted infection screening results for DuDHS trial participants.

| Variable | Overall n (%) | Immediate (N=26) n (%) | Deferred (N=26) n (%) | P-Value |
|------------------|------------------|------------------------------|-----------------------------|---------|
| Chlamydia (n=47) | 2 (4) | 1 (4) | 1 (4) | 1 |
| Gonorrhea (n=47) | 2 (4) | 1 (4) | 1 (4) | 1 |
| Syphilis (n=49) | 1 (2) | 0 | 1 (4) | 1 |
| Any STI (n=49) | 4 (4) | 1 (4) | 3 (12) | 0.609 |

Missing responses removed. **Bolded text** indicates significant results at $P < 0.05$.

Results

Table 3. Sexual history and HIV PrEP desire and use history among DuDHS trial participants.

| Variable | Overall n (%) | Immediate (N=26) n (%) | Deferred (N=26) n (%) | P-Value |
|---|-----------------------|------------------------------|-----------------------------|----------------|
| Main sex partner (yes) | 10 (19) | 7 (27) | 3 (11) | 0.264 |
| Sex with condom receptive (yes) | 21 (40) | 11 (42) | 10 (38) | 0.815 |
| Sex with condom insertive (yes) | 17 (33) | 6 (23) | 11 (42) | 0.05 |
| Sex without condom receptive (yes) | 28 (54) | 16 (61) | 12 (46) | 0.703 |
| Sex without condom insertive (yes) | 28 (54) | 16 (61) | 12 (46) | 0.703 |
| Sex with drugs | | | | |
| Methamphetamines (yes) | 7 (13) | 5 (19.2) | 2 (8) | 0.403 |
| Poppers (yes) | 24 (46) | 14 (54) | 10 (38) | 0.483 |
| Drunk/High (yes) | 11 (21) | 7 (27) | 4 (15) | 0.143 |
| Tried to access HIV PrEP before (yes) | 31 (60) | 14 (54) | 17 (65) | 0.194 |
| Previously used HIV PrEP (yes) | 27 (52) | 12 (46) | 15 (58) | 0.395 |
| Alcohol use (yes) | 32 (61) | 18 (69) | 14 (54) | 0.582 |
| Substance use (yes) | 36 (69) | 19 (73) | 17 (65) | 0.548 |
| | Median (Q1-Q3) | Median (Q1-Q3) | Median (Q1-Q3) | P-Value |
| Self-reported lifetime Syphilis (cases) | 1 (1-2) | 1 (1-2) | 1 (1-1) | 0.716 |
| Self-reported lifetime GC + CT (cases) | 2 (0-5) | 2 (0-4) | 2 (0-5) | 0.987 |

Abbreviations: GC = Gonorrhea. CT = Chlamydia.

Missing responses removed. **Bolded text** indicates significant results at $P < 0.05$.

Conclusions

- A history of multiple chlamydia and gonorrhoea diagnoses, previous HIV PrEP use, substance use, alcohol use, and not having a main sex partner were common among DuDHS trial participants.
- Understanding the characteristics of MSM interested in combined HIV and syphilis PrEP may help to inform its potential uptake and effectiveness in a larger RCT.
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- Any questions or comments, please contact:
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