# ADHERENCE MARKERS FOR DOXY-PEP IN PLASMA AND URINE

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## BACKGROUND

Clinical trials have shown that a single 200 mg oral dose of doxycycline taken up to 72 hours after sex (Doxy-PEP) can protect men who have sex with men (MSM) from chlamydia, syphilis and gonorrhea[1,2]. However, a clinical trial among heterosexual women was unable to show similar efficacy in STI prevention[3]. Low efficacy has been attributed to poor adherence and highlights the importance of objective adherence monitoring in future clinical trials. We examined doxycycline concentrations in urine and plasma following a single oral dose of doxycycline to identify objective adherence markers of Doxy-PEP dosing.

## METHODS

Blood and urine was collected from 11 MSM and 9 cisgender women at 1, 2, 4, 8, 24, 48, 72, 96 and 168 hours after a single 200 mg oral dose of delayed-release doxycycline hyclate. Plasma and urine doxycycline concentrations were measured using liquid chromatography tandem mass spectrometry (LC-MS/MS) with a lower limit of quantification of 0.010 µg/mL. Adherence indicators were identified as 10$^{th}$ percentile concentration at each time point.

**Plasma and urine doxycycline concentrations can indicate Doxy-PEP dosing within the last 4 and 7 days, respectively.**

## RESULTS

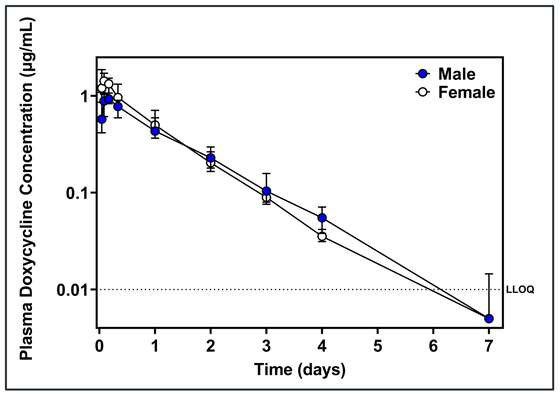



**Figure 1:** Plasma doxycycline concentrations among male and female participants collected after a single oral dose of doxycycline. Concentrations are presented as median and interquartile range. Lower limit of quantification (LLOQ) is noted by the dotted line (0.010 µg/mL).

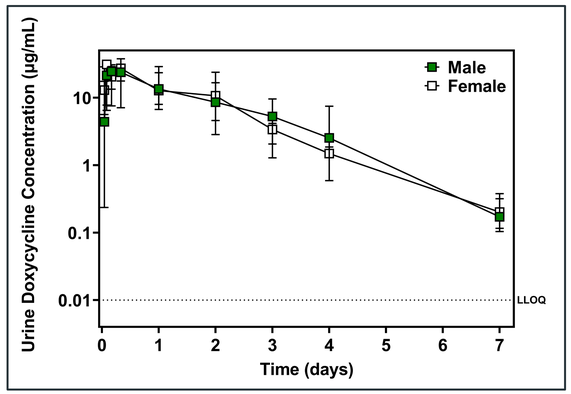



**Figure 2:** Urine doxycycline concentrations among male and female participants collected after a single oral dose of doxycycline. Concentrations are presented as median and interquartile range. Lower limit of quantification (LLOQ) is noted by the dotted line (0.010 µg/mL).

**Table 1: Participant demographics**

| | Male (n=11) | Female (n=9) |
|---|---|---|
| **Age (years)** | 38 (24 – 48) | 34 (26 – 44) |
| **Weight (kg)** | 77 (70 – 122) | 70 (60 – 98) |
| **Height (cm)** | 178 (175 – 183) | 165 (165 – 169) |
| **Body-mass index (kg/m²)** | 25 (22 – 41) | 24 (24 – 36) |
| **Race/Ethnicity** | | |
| Black | 6 | 5 |
| White | 5 | 4 |

**Table 2: Adherence indicators of Doxy-PEP dosing**

| | Days After Dosing | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 7 |
| **Plasma Adherence Indicator (µg/mL)** | | | | | |
| **Male** | 0.312 | 0.147 | 0.069 | 0.029 | <LOQ |
| **Female** | 0.370 | 0.147 | 0.053 | 0.030 | <LOQ |
| **Combined** | 0.342 | 0.147 | 0.066 | 0.030 | <LOQ |
| **Urine Adherence Indicator (µg/mL)** | | | | | |
| **Male** | 3.150 | 1.262 | 0.197 | 0.411 | 0.137 |
| **Female** | 2.655 | 2.710 | 0.304 | 0.110 | <LOQ |
| **Combined** | 3.072 | 1.455 | 0.283 | 0.351 | 0.072 |

## CONCLUSIONS

- Measurable doxycycline concentrations persist in plasma and urine 4 and 7 days after dosing, respectively.
- Plasma adherence indicators were determined to be:
  - 1 day: 0.34 µg/mL
  - 4 days: 0.03 µg/mL
- Urine adherence indicators were determined to be:
  - 1 day: 3.00 µg/mL
  - 4 days: 0.35 µg/mL
  - 7 days: 0.07 µg/mL
- Indicators can be used in clinical studies to better assess Doxy-PEP adherence and its impact on efficacy.

## REFERENCES

1. Molina JM *et al. Lancet Infect Dis* 2018; 18 (3): 308-17.
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3. Stewart J et al. N Engl J Med 2023; 389 (25): 2331-40.

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