P089

1.5-year clinical outcomes from a pilot program of non-occupational post-exposure prophylaxis (nPEP) in Vancouver, British Columbia (BC).

Jayaram Pai[1], Marianne Harris[2,3], Wendy Zhang[1], Susan Shergold[1], Guillaume Colley[1], Linda Akagi[1], Silvia Guillemi[1,2,3], Valentina Montessori[1,3], David Moore[1,2], Irene Day[1], Julio Montaner[1,3], Mark Hull[1,3]

1 – British Columbia Centre for Excellence in HIV/AIDS; 2 – University of British Columbia, Department of Family Practice; 3 – University of British Columbia, Division of AIDS.

Background

- In BC, provincial coverage of nPEP for HIV exposures from consensual sex or needle-sharing has not been available.
- In July 2012, the BC Centre for Excellence in HIV/AIDS launched a 2-year pilot program offering nPEP at six sites in downtown Vancouver:
  - A tertiary care hospital (St. Paul's Hospital, SPH) via its Emergency Department (SPH-ED) and Outpatient HIV Clinic (SPH-OHC).
  - A family practice that specializes in LGBTQ patients and those living with HIV (Spectrum Clinic, SC).
  - Two community-based HIV/STI clinics serving the LGBTQ community (Health Initiative for Men Sexual Health Centre, HIM-SHC; and Bute Street Clinic, BSC).
  - A community health centre located in the Downtown Eastside, serving more marginalized populations living with HIV and at-risk for HIV (Downtown Community Health Centre, DCHC)
- Costs of antiretroviral (ARV) prophylactic medications were covered by provincial drug insurance (BC PharmaCare).
- We present updated results of this pilot program over 18 months of operation.

Methods

- **nPEP protocol:** A 7-day ARV starter-kit containing lopinavir/ritonavir, tenofovir and lamivudine was administered to individuals within 72 hours after a potential HIV exposure. Re-assessment of the exposure event after 7 days determined the need to continue a full 28-day regimen. These patients completed their clinical follow-up at SPH-OHC (patients who presented to DCHC were able to complete their follow-up there).
- **Data collection:** Standardized clinical data were collected weekly by physicians or nurses for 28 days, and included: the route of HIV exposure (e.g. unprotected intercourse or needle sharing), source risk group (e.g. known HIV positive, injection drug user, sex trade worker, men who have sex with men), treatment-related side-effects, treatment discontinuations and regimen changes.
- **Analysis:** We examined data from July 2012 to December 2013. Among individuals prescribed 28-days of nPEP, characteristics of those who completed therapy were compared to those who discontinued early using Fisher's Exact and Wilcoxon tests.

Results

- A total of **323 individuals initiated nPEP**. Of these, 41 encounters were from 20 individuals with repeat nPEP initiations (median = 2, range = 2 - 3).

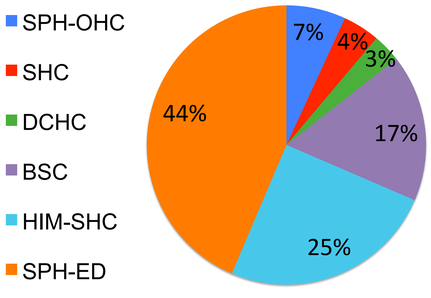

Figure 1. Distribution of nPEP users in Vancouver by pilot site.

Results Continued

- **Site distribution:** Approximately 81% of nPEP users presented to one of three sites: SPH-ED (n = 133, 44%), followed by HIM-SHC (n = 76, 25%), and BSC (n = 52, 17%). The remaining 14% presented to one of the other three sites (see **Figure 1**).
- **Demographics**: The majority were male (n = 143, 93.3%), median age was 32 years (IQR = 27 - 41) and unprotected anal intercourse was the most commonly reported exposure event (n = 242, 75%). Only 30 patients (9%) reported needle-sharing as their exposure event. Median exposure-to-assessment time was 21 hours (IQR = 12 - 39).
- **Follow-up:** Prior to the 7-day re-assessment, 96/323 (30%) were lost-to-follow-up (see **Figure 2A**); of the remaining 227 individuals, 205 (90%) were recommended and prescribed the full 28-days of nPEP. Individuals who were determined to have had a very low probability of HIV-exposure at re-assessment were not recommended to continue nPEP past the 7-day starter kit (22/227, 10%) (see **Figure 2B**).
- **Comparison (completed nPEP vs early discontinuation):** 190/205 individuals had the opportunity to complete treatment at the time of this analysis, and of these, 152 (80%) completed the full course, while 38 (20%) did not. For those who completed therapy, there were no significant differences by age, gender, exposure type, source of HIV exposure, or treatment side effects when compared to those who discontinued early (see **Table 1**). However, those who completed therapy were more likely to have presented to SPH-ED than any other nPEP pilot site (p = 0.035).

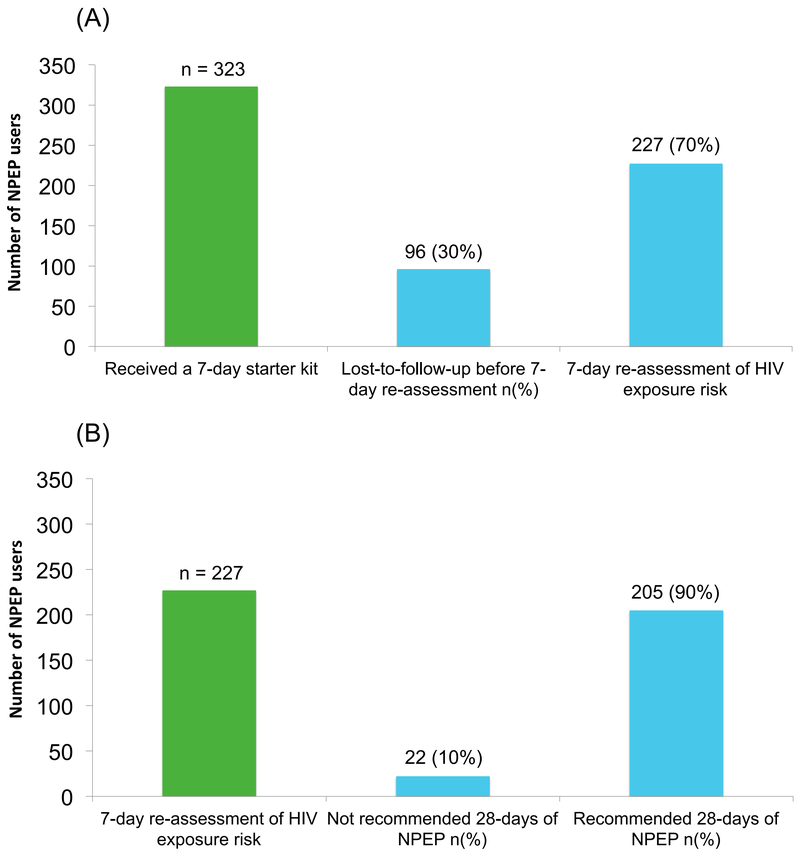

Figure 2. Follow-up outcomes of nPEP users.
A) Individuals who received a 7-day nPEP start kit (green bar); number of repeat users; number of lost-follow-up before 7-day reassessment; number at 7-day reassessment.
B) Individuals at 7-day reassessment (green bar); number not recommended 28-days of nPEP; number recommended 28-days of nPEP.

Results Continued

Table 1. Characteristics of individuals recommended 28 days of nPEP.

Characteristics	Early Discontinuation of nPEP (n = 38)	Completed nPEP (n = 152)	p-value
Age - median (IQR)	32 (27 - 40)	33 (27 - 42)	0.991
Gender – no. (%):			
Female	4 (10.5%)	6 (4.0%)	0.117
Male	34 (89.5%)	145 (96.0%)	
Hours between exposure and assessment – median (IQR)	19 (11 - 40)	24 (13 - 38)	0.512
Type of exposure – no. (%):			
Needle sharing	0	6 (4.0%)	0.600
Unprotected vaginal intercourse	4 (10.8%)	19 (12.7%)	0.990
Unprotected anal intercourse	33 (89.2%)	128 (85.3%)	0.791
Receptive oral with ejaculation	5 (13.5%)	11 (7.3%)	0.320
Side effects – no. (%):			
Nausea	20 (57.1%)	97 (64.2%)	0.434
Vomiting	3 (9.1%)	18 (12.0%)	0.771
Diarrhea	28 (77.8%)	118 (78.1%)	0.962
Fatigue	26 (74.3%)	113 (75.3%)	0.897
Source of HIV exposure – no. (%):			
Known to patient	21 (58.3%)	92 (61.3%)	0.850
Gender:			
Female	1 (2.9%)	6 (8.7%)	0.476
Male	34 (97.1%)	135 (91.2%)	
Risk group:			
Known HIV positive	17 (47.2%)	55 (36.4%)	0.256
Injection drug user	0	12 (7.9%)	0.127
Men who have sex with men	27 (75.0%)	115 (76.2%)	0.990
Sex trade worker	3 (8.3%)	16 (10.6%)	0.990

- **Side effects**: Common side effects of all 323 nPEP users were diarrhea (n = 164, 51%) fatigue (n = 153, 47%) and nausea (n = 111, 34.%); however, only 3 individuals (0.9%) discontinued and 26 (8%) changed their nPEP regimen due to side effects.
- **HIV sero-conversions:** No sero-conversions were reported during the four-week treatment period. Additionally, no sero-conversions were reported among those who received an HIV test at 6-weeks post-exposure (n = 85).

Summary and Conclusion

- Between July 2012 – December 2013, 323 individuals initiated nPEP through this pilot program in Vancouver, BC. Unprotected anal intercourse was the most commonly reported HIV exposure event.
- Although nPEP was well-tolerated, 30% of patients who initiated nPEP were lost-to-follow-up before re-assessment of exposure risk and continuation of ARVs could be determined. Additionally, of those who were recommended the full 28-day course, 20% did not complete treatment.
- Additional interventions are needed to support nPEP adherence and clinical follow-up, including HIV testing at 6 weeks post-exposure.

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For more information contact: jpai@cfenet.ubc.ca, or visit http://cfenet.ubc.ca/npep

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