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# Substitution of tenofovir for nucleoside analogues in virologically controlled HIV-infected patients co-infected with hepatitis C virus: TEN-SWITCH

J Grebely<sup>1</sup>, L Gallagher<sup>2</sup>, E Knight<sup>2</sup>, K Genoway<sup>2</sup>, M Storms<sup>3</sup>, HK Tossonian<sup>3</sup>, M Hosseina<sup>3</sup>, G Showler<sup>4</sup>, JD Raffa<sup>5</sup>, C Fraser<sup>4</sup>, F Duncan<sup>6</sup> and B Conway\*<sup>3</sup>

Address: <sup>1</sup>National Centre in HIV Epidemiology and Clinical Research, University of New South Wales, Darlinghurst, Australia, <sup>2</sup>Department of Anesthesiology, Pharmacology and Therapeutics, University of British Columbia, Vancouver, Canada, <sup>3</sup>Department of Anesthesiology, Pharmacology and Therapeutics, University of British Columbia, Vancouver, British Columbia, Canada, <sup>4</sup>Cool Aid Community Health Centre, Victoria, British Columbia, Canada, <sup>5</sup>Department of Statistics and Actuarial Science, University of Waterloo, Waterloo, Ontario, Canada and <sup>6</sup>Pender Community Health Centre, Vancouver Coastal Health, Vancouver, British Columbia, Canada

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#### **Background**

Treatment of hepatitis C virus (HCV) in HCV/HIV coinfected patients requires the simultaneous management of two complex regimens, including addressing potential drug interactions between HCV and HIV medications.

#### **Methods**

TEN-SWITCH is a prospective, observational study to evaluate the impact of substituting tenofovir (TDF) for other nucleoside analogues in virologically controlled HIV-infected patients (HIV RNA <400 copies/mL) on maintenance of virologic suppression and immune status in HCV/HIV co-infected subjects. Adverse events and HCV treatment uptake following a switch to TDF were also evaluated.

#### Summary of results

Among 23 subjects enrolled (mean age 45 years, 83% male), 44% were HCV genotype 3, 65% were receiving methadone and 87% reported a history of illicit and injection drug use. The median number of previous NRTIs, NNRTIs and PIs were 2 (range: 0–4), 1 (range: 0–2) and 0 (range: 0–4), respectively. Prior to switch, subjects received PI- (n = 18, LPV/RTV = 9, IDV/RTV = 1, SQV/RTV = 1, ATV/RTV = 2, ATV = 4) or NNRTI-based (n = 5, EFV =

2, NVP = 3, DLV = 1) HAART in combination with either 3TC/DDI (n = 14), ABC/DDI (n = 2), FTC/DDI (n = 1), 3TC/d4T (n = 4), 3TC/AZT (n = 1) or ABC/AZT (n = 1). Median baseline CD4+ count and HIV RNA were 350 (range: 40-999) cells/mm<sup>3</sup> and <50 (range: 0-75) copies/ mL. Overall, 100% and 91% had HIV-RNA <400 copies/ mL and <50 copies/mL, respectively. Among the 18 subjects having completed 12 months of follow-up, two subjects (11%) discontinued TDF following a switch (one due to adverse events, nausea and vomiting likely associated with addition of RTV to unboosted ATV regimen; one due to non-adherence). Two other adverse events that did not require therapy discontinuation were observed (one vertigo, one - nausea with the addition of RTV). At 12 months of follow-up, the median CD4+ count and HIV-RNA were 530 (range: 180-999) cells/mm<sup>3</sup> and <50 (range: 0-82) copies/mL. At 12 months (intent to treat), 89% and 83% had HIV-RNA <400 copies/mL and <50 copies/mL, respectively. Of 18 subjects, three (17%) initiated treatment for HCV infection.

### **Conclusion**

Switching nucleosides in an effective HAART regimen to TDF in preparation for HCV treatment to address potential ribavirin/nucleoside interactions is a safe intervention

<sup>\*</sup> Corresponding author

not associated with loss of virologic or immunologic efficacy of the regimen.

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