

Unpacking TasP and its implications

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pour les essais VIH des IRSC

SFU

Boozhoo!

I would like to begin by acknowledging the Indigenous peoples of this beautiful country. In particular, I acknowledge the *Gadigal* clan of the *Eora* nation. They are the traditional owners of the lands and waters of Sydney's inner city. I am grateful for receiving such a warm welcome. It is also such an honour to enjoy these lands that they, and their ancestors, have cared for so well.

I would like to thank the Organising Committee for their vision and hard work, as well as the opportunity to present. I would also like to thank the Elders, other speakers, and each of participants for sharing this time and understanding together.

Miigwech!



Nipissing First Nation

“Each man’s and woman’s liberty was absolute and inviolable. A Nipissing came as near as possible to Rousseau’s perfect and ‘ideal man’. He was untainted by civilization, did what he liked, and was moved only by natural impulses, and if, the Nipissing was not a free man and independent man, then there was no absolute freedom or independence on earth.”

- Jean Recollet in *The Jesuit Relations*



Desmond (Algonquin, Mattawa FN), Mary (Ojibwa / Mohawk, Nipissing FN) and daughter Mary (my mother)



Raymond (my father), of mixed European ancestry

Other acknowledgements

- ★ My positive Indigenous brothers and sisters, especially our veteran warriors
- ★ Elders, Healers and Knowledge Keepers
- ★ Indigenous colleagues - community and academia
- ★ PhD / CTN Supervisory Committee, especially Will Small, my Senior Supervisor
- ★ My husband, family and friends



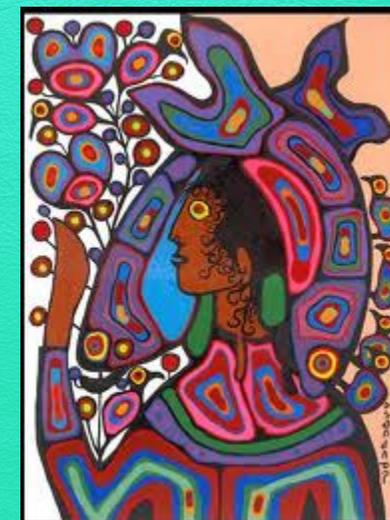
Disclosures

- ★ Bristol-Myers Squibb:
 - ★ Provided honoraria for training the trainers as part of their support of CTN / CAAN
 - ★ I donated my honoraria to charity
 - ★ I subsequently provided training without accepting honoraria



Outline

- ★ ART changing philosophy
- ★ TasP vs TasT?
- ★ Evidence, support
- ★ Ethical considerations
- ★ Current challenges
- ★ Future directions



ART changing philosophy

- * In 1996, ART was recommended for all PLHA with a CD4+ count < 500.
- * But treatment initiation was delayed until later disease stages because of drug toxicities / side effects, thought to result in inadequate adherence leading to increased resistance.
- * Late starts, drug holidays / strategic treatment interruptions, short-courses through pregnancy, and so on.
- * As ART regimens have improved, treatment initiation has moved earlier and earlier.
- * Current ART regimens highly effective, providing almost similar life expectancy enjoyed by those without HIV ...

Kitahata, MM et al. (2009). Effect of early versus deferred antiretroviral therapy for HIV on survival. NEJM 360(18).

TasP versus TasT?

- * Origins: extension from vertical (mother to child) and horizontal (serodiscordant couples) transmission prevention
- * Influences: mathematical modelling and health economics, especially regarding LEDCs / NICs
- * Estimated 42 million PLHA globally
- * ¼ in sub-Saharan Africa, most in LEDCs / NICs
- * Estimated global drug costs are US\$22-24 billion/yr by 2015
- * But amongst developed countries, autonomy and right for health have priority



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CD4+ Count–Guided Interruption of Antiretroviral Treatment

The Strategies for Management of Antiretroviral Therapy (SMART) Study Group*

ABSTRACT

BACKGROUND: Despite declines in morbidity and mortality with the use of combination antiretroviral therapy, its effectiveness is limited by adverse events, problems with adherence, and resistance of the human immunodeficiency virus (HIV).

METHODS: We randomly assigned persons infected with HIV who had a CD4+ cell count of more than 350 per cubic millimeter to the continuous use of antiretroviral therapy (the viral suppression group) or the episodic use of antiretroviral therapy (the drug conservation group). Episodic use involved the deferral of therapy until the CD4+ count decreased to less than 250 per cubic millimeter and then the use of therapy until the CD4+ count increased to more than 350 per cubic millimeter. The primary end point was the development of an opportunistic disease or death from any cause. An important secondary end point was major cardiovascular, renal, or hepatic disease.

RESULTS: A total of 5472 participants (2720 assigned to drug conservation and 2752 to viral suppression) were followed for an average of 16 months before the protocol was modified for the drug conservation group. At baseline, the median and nadir CD4+ counts were 597 per cubic millimeter and 250 per cubic millimeter, respectively, and 71.7% of participants had plasma HIV RNA levels of 400 copies or less per milliliter. Opportunistic disease or death from any cause occurred in 120 participants (3.3 events per 100 person-years) in the drug conservation group and 47 participants (1.3 per 100 person-years) in the viral suppression group (hazard ratio for the drug conservation group vs. the viral suppression group, 2.6; 95% confidence interval [CI], 1.9 to 3.7; P<0.001). Hazard ratios for death from any cause and for major cardiovascular, renal, and hepatic disease were 1.8 (95% CI, 1.2 to 2.9; P=0.007) and 1.7 (95% CI, 1.1 to 2.5; P=0.009), respectively. Adjustment for the latest CD4+ count and HIV RNA level (as time-updated covariates) reduced the hazard ratio for the primary end point from 2.6 to 1.5 (95% CI, 1.0 to 2.1).

CONCLUSIONS: Episodic antiretroviral therapy guided by the CD4+ count, as used in our study, significantly increased the risk of opportunistic disease or death from any cause, as compared with continuous antiretroviral therapy, largely as a consequence of lowering the CD4+ cell count and increasing the viral load. Episodic antiretroviral therapy does not reduce the risk of adverse events that have been associated with antiretroviral therapy. (ClinicalTrials.gov number, NCT00027352.)

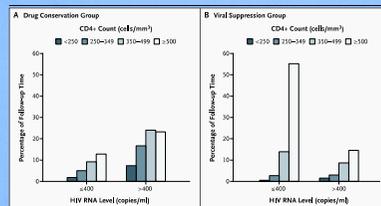


Figure 1. Percentage of Follow-up Time during Which Participants Had a Specified CD4+ Count and HIV RNA Level. For 28.8% of the 1666 person-years of follow-up in the drug conservation group (Panel A), the HIV RNA level was 400 copies per milliliter or less. Patients received antiretroviral therapy during 20% of the follow-up time. For 72.3% of the 1701 person-years of follow-up in the viral suppression group (Panel B), the HIV RNA level was 400 copies per milliliter or less. Patients received antiretroviral therapy during 94% of the follow-up time.

“Episodic antiretroviral therapy guided by the CD4+ count ... significantly increased the risk of opportunistic disease or death from any cause, as compared with continuous antiretroviral therapy, largely as a consequence of lowering the CD4+ cell count and increasing the viral load.”

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*The members of the SMART study group are listed in the Appendix.

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The NEW ENGLAND JOURNAL of MEDICINE

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Prevention of HIV-1 Infection with Early Antiretroviral Therapy

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ABSTRACT

BACKGROUND: Antiretroviral therapy that reduces viral replication could limit the transmission of human immunodeficiency virus type 1 (HIV-1) in serodiscordant couples.

METHODS: In nine countries, we enrolled 1763 couples in which one partner was HIV-1–positive and the other was HIV-1–negative. 54% of the subjects were from Africa, and 50% of infected partners were men. HIV-1–infected subjects with CD4 counts between 350 and 550 cells per cubic millimeter were randomly assigned in a 1:1 ratio to receive antiretroviral therapy either immediately (early therapy) or after a decline in the CD4 count or the onset of HIV-1–related symptoms (delayed therapy). The primary prevention end point was linked HIV-1 transmission in HIV-1–negative partners. The primary clinical end point was the earliest occurrence of pulmonary tuberculosis, severe bacterial infection, a World Health Organization stage 4 event, or death.

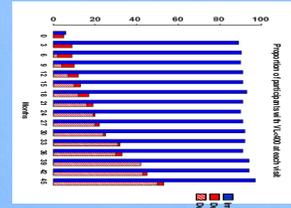
RESULTS: As of February 21, 2011, a total of 39 HIV-1 transmissions were observed (incidence rate, 1.2 per 100 person-years; 95% confidence interval [CI], 0.9 to 1.7); of these, 28 were virologically linked to the infected partner (incidence rate, 0.9 per 100 person-years; 95% CI, 0.6 to 1.3). Of the 28 linked transmissions, only 1 occurred in the early-therapy group (hazard ratio, 0.04; 95% CI, 0.01 to 0.27; P=0.001). Subjects receiving early therapy had fewer treatment end points (hazard ratio, 0.59; 95% CI, 0.40 to 0.88; P=0.01).

CONCLUSIONS: The early initiation of antiretroviral therapy reduced rates of sexual transmission of HIV-1 and clinical events, indicating both personal and public health benefits from such therapy. (Funded by the National Institute of Allergy and Infectious Diseases and others; HPTN 052 ClinicalTrials.gov number, NCT00074981.)

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*Other members of the HIV Prevention Trials Network (HPTN) 052 Study Team are listed in the Supplementary Appendix, available at NEJM.org.

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HPTN 052: Consistent Use of ART

“In this trial, we found that early antiretroviral therapy had a clinical benefit for both HIV-1–infected persons and their uninfected sexual partners.”

Effect of Early versus Deferred Antiretroviral Therapy for HIV on Survival

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BACKGROUND: The optimal time for the initiation of antiretroviral therapy for asymptomatic patients with human immunodeficiency virus (HIV) infection is uncertain.

DESIGN: We conducted two parallel analyses involving a total of 3757 asymptomatic patients with HIV infection in the United States and Canada who received medical care during the period from 1990 through 2005. None of the patients had undergone previous antiretroviral therapy. In each group, we stratified the patients according to the CD4+ count (351 to 500 cells per cubic millimeter or >500 cells per cubic millimeter) at the initiation of antiretroviral therapy. In each group, we compared the relative risk of death for patients who initiated therapy when the CD4+ count was above each of the two thresholds of interest (early therapy group) with that of patients who deferred therapy until the CD4+ count fell below these thresholds (deferred-therapy group).

RESULTS: In the first analysis, which involved 3862 patients, 2084 (29%) initiated therapy at a CD4+ count of 351 to 500 cells per cubic millimeter, and 678 (78%) deferred therapy. After adjustment for calendar year, cohort of patients, and demographic and clinical characteristics, among patients in the deferred-therapy group there was an increase in the risk of death of 69%, as compared with that in the early-therapy group (relative risk in the deferred-therapy group, 1.69; 95% confidence interval [CI], 1.26 to 2.26; P<0.0001). In the second analysis involving 9155 patients, 2220 (24%) initiated therapy at a CD4+ count of more than 500 cells per cubic millimeter and 6955 (76%) deferred therapy. Among patients in the deferred-therapy group, there was an increase in the risk of death of 94% (relative risk, 1.94; 95% CI, 1.37 to 2.7%; P<0.001).

CONCLUSIONS: The early initiation of antiretroviral therapy before the CD4+ count fell below two prespecified thresholds significantly improved survival, as compared with deferred therapy.

Table 3. Risk of Death Associated with Deferral of Antiretroviral Therapy, According to CD4+ Count at Baseline, with Adjustment for HIV RNA Level, Age, and Sex.*

Variable	351-to-500 CD4+ Count Relative Risk (95% CI)	P Value	More-Than-500 CD4+ Count Relative Risk (95% CI)	P Value
Without inclusion of HIV RNA data				
Deferral of antiretroviral therapy	1.69 (1.26–2.26)	<0.001	1.94 (1.33–2.79)	<0.001
Female sex	1.21 (0.88–1.64)	0.24	1.85 (1.33–2.59)	<0.001
Older age (per 10-yr increment)	1.68 (1.48–1.91)	<0.001	1.83 (1.62–2.06)	<0.001
Baseline CD4+ count (per 100 cells/mm ³)	1.13 (0.72–1.78)	0.59	0.93 (0.81–1.09)	0.03
With inclusion of HIV RNA data				
Deferral of antiretroviral therapy	1.63 (1.21–2.19)	0.002	1.85 (1.25–2.86)	0.006
Female sex	1.47 (1.02–2.12)	0.04	1.35 (0.92–1.95)	0.20
Older age (per 10-yr increment)	1.89 (1.66–2.11)	<0.001	1.81 (1.58–2.07)	<0.001
Baseline CD4+ count (per 100 cells/mm ³)	0.74 (0.55–1.00)	0.06	0.97 (0.83–1.05)	0.45
Baseline HIV RNA level (per log ₁₀ copies/ml)	1.11 (0.96–1.28)	0.15	1.13 (0.94–1.33)	0.14

*The P value for interaction between the two CD4+ count thresholds was 0.001 for patients with the use of HIV RNA data.

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“Significant advances in our understanding of the role of HIV infection in inflammation and immune activation resulting in potentially irreversible immune-system and end-organ damage have renewed the impetus for earlier treatment of HIV.”

Viremia Copy-Years Predicts Mortality Among Treatment-Naive HIV-Infected Patients Initiating Antiretroviral Therapy

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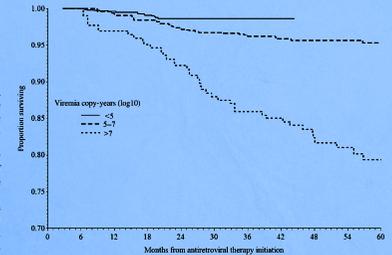
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BACKGROUND: Cross-sectional plasma human immunodeficiency virus (HIV) viral load (VL) measures have proven invaluable for clinical and research purposes. However, cross-sectional VL measures fail to capture cumulative plasma HIV burden longitudinally. We evaluated the cumulative effect of exposure to HIV replication on mortality following initiation of combination antiretroviral therapy (ART).

DESIGN: We included treatment-naive HIV-infected patients starting ART from 2000 to 2008 at 8 Centers for AIDS Research Network of Integrated Clinical Systems sites. Viremia copy-years, a time-varying measure of cumulative plasma HIV exposure, were determined for each patient using the area under the VL curve. Multivariable Cox models were used to evaluate the independent association of viremia copy-years for all-cause mortality.

RESULTS: Among 2027 patients contributing 6579 person-years of follow-up, the median viremia copy-years was 5.3 log₁₀ copy × year (interquartile range: 4.2–6.3 log₁₀ copy × year), and 85 patients (4.2%) died. When evaluated separately, viremia copy-years (hazard ratio [HR] = 1.81 per log₁₀ copy × year; 95% confidence interval [CI], 1.51–2.18 per log₁₀ copy × year), 24-week VL (1.74 per log₁₀ copies/mL; 95% CI, 1.48–2.04 per log₁₀ copies/mL), and most recent VL (HR = 1.89 per log₁₀ copies/mL; 95% CI, 1.63–2.20 per log₁₀ copies/mL) were associated with increased mortality. When simultaneously evaluating VL measures and controlling for other covariates, viremia copy-years increased mortality risk (HR = 1.64 per log₁₀ copy × year; 95% CI, 1.40–1.94 per log₁₀ copy × year), whereas non-cross-sectional VL measure was independently associated with mortality.

CONCLUSIONS: Viremia copy-years predicted all-cause mortality independent of traditional, cross-sectional VL measures and time-updated CD4+ T-lymphocyte count in ART-treated patients, suggesting cumulative HIV replication causes harm independent of its effect on the degree of immunodeficiency.



“Cumulative HIV replication causes harm independent of its effect on degree of immunodeficiency.”

Effects of early versus delayed initiation of antiretroviral treatment on clinical outcomes of HIV-1 infection: results from the phase 3 HPTN 052 randomised controlled trial

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TasT/P - Support

Initiating Antiretroviral Therapy in Treatment-Naive Patients (Last updated May 1, 2014; last reviewed May 1, 2014)

Panel's Recommendations

- Antiretroviral therapy (ART) is recommended for all HIV-infected individuals to reduce the risk of disease progression.
 - The strength of and evidence for this recommendation vary by pretreatment CD4 T lymphocyte (CD4) cell count: CD4 count <350 cells/mm³ (AI); CD4 count 350 to 500 cells/mm³ (AII); CD4 count >500 cells/mm³ (BII).
- ART is also recommended for HIV-infected individuals to prevent of transmission of HIV.
 - The strength of and evidence for this recommendation vary by transmission risks: perinatal transmission (AI); heterosexual transmission (AI); other transmission risk groups (AII).
- Patients starting ART should be willing and able to commit to treatment and understand the benefits and risks of therapy and the importance of adherence (AIII). Patients may choose to postpone therapy, and providers, on a case-by-case basis, may elect to defer therapy on the basis of clinical and/or psychosocial factors.

Rating of Recommendations: A = Strong; B = Moderate; C = Optional

Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

AIDSInfo. (2014). Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents.

The screenshot shows the PositiveLite.com website interface. At the top, there's a navigation bar with 'Home', 'News', 'Contributors', 'Market Place', and 'More...'. Below that, a search bar is visible. The main content area features a large article titled 'THE COMMUNITY SPEAKS ON TREATMENT AS PREVENTION' dated Sunday, 02 March 2014. The article includes a sub-header 'Building Consensus: One thumb at a time.' and a graphic showing several hands giving a thumbs-up. To the right of the article, there's a sidebar with a 'Home' button and a 'News' section. Below the article, there's a quote: 'This isn't a simple thing, which is why it took a year to get together (and it still isn't perfect)... it came out of a conviction that disagreement within the community (both of PLAs, and of medical researchers/programmers) about how to use of Treatment as Prevention was harmful, and we needed some basic principles most people could sign up to that, without being bland, would be balanced, and have at their base one axiom: the right to patient choice, freedom, dignity and agency.' The website footer includes the URL 'http://www.positivelite.com/component/option,com_content/view/the-community-speaks-on-treatment-as-prevention' and 'Page 1 of 7'.

“PositiveLite.com has long supported treatment as prevention strategies. We believe treatment as prevention embodies the empowerment of people living with HIV like few other opportunities to impact one’s individual health and those we interact with while contributing to an end to the epidemic.”

TasT/P: Ethical considerations

- ★ Pharmacovigilance
 - ★ Increased resistance, prolonged exposure to ART toxicities
 - ★ Available studies not supporting this ... so far
- ★ Balancing individual versus societal interests
 - ★ Social libertarian vs communitarian frameworks
 - ★ TasP seen as burdening the individual in favour of public health
 - ★ Medical ethics:
 - ★ Individual autonomy, beneficence and non-maleficence
 - ★ Public beneficence

Knight, R. et al. (2014). A scoping study to identify opportunities to advance the ethical implementation and scale-up of HIV treatment as prevention: priorities for empirical research. BMC Med Ethics. 3:15:54.

TasT/P: Ethical considerations

- ★ Cultural safety and health systems issues
 - ★ Power relations (patient-to-MD, patient-to-health systems, services, policies)
 - ★ Targeting, early testing but poor engagement / retention in the care cascade
 - ★ ART scarcity (developed vs LEDCs/NICs; treatment priorities)
- ★ Efficacy versus effectiveness
 - ★ Evidence from the ideal world of drug trials ... what about adherence in the real world?
- ★ Lifetime commitment in the face of Indigenous determinants of health
 - ★ Many question our ability to address distal causes of HIV, given resource allocation to TasT/P

Knight, R. et al. (2014). A scoping study to identify opportunities to advance the ethical implementation and scale-up of HIV treatment as prevention: priorities for empirical research. BMC Med Ethics. 3:15:54.

TasT/P - an Indigenous take

- * Solidifying evidence base and support
- * ART as life-saving, life-giving
- * Approaching similar life expectancies as negative people
- * But too often, TasT/P = strictly biomedical solution to a problem that is much greater
- * My concern that TasT/P will widen the existing gap, that we will be left behind

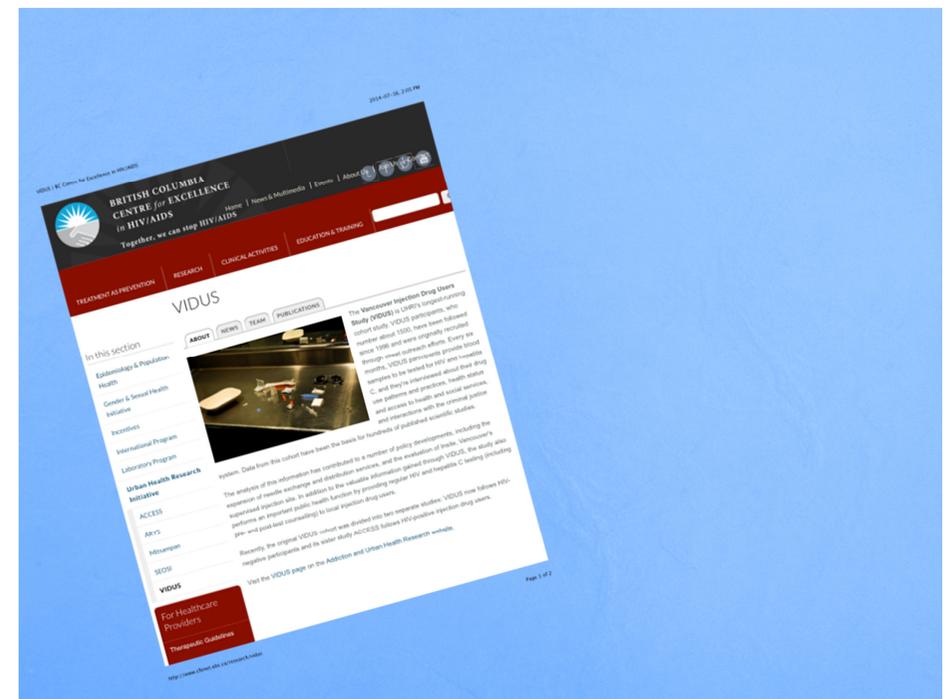


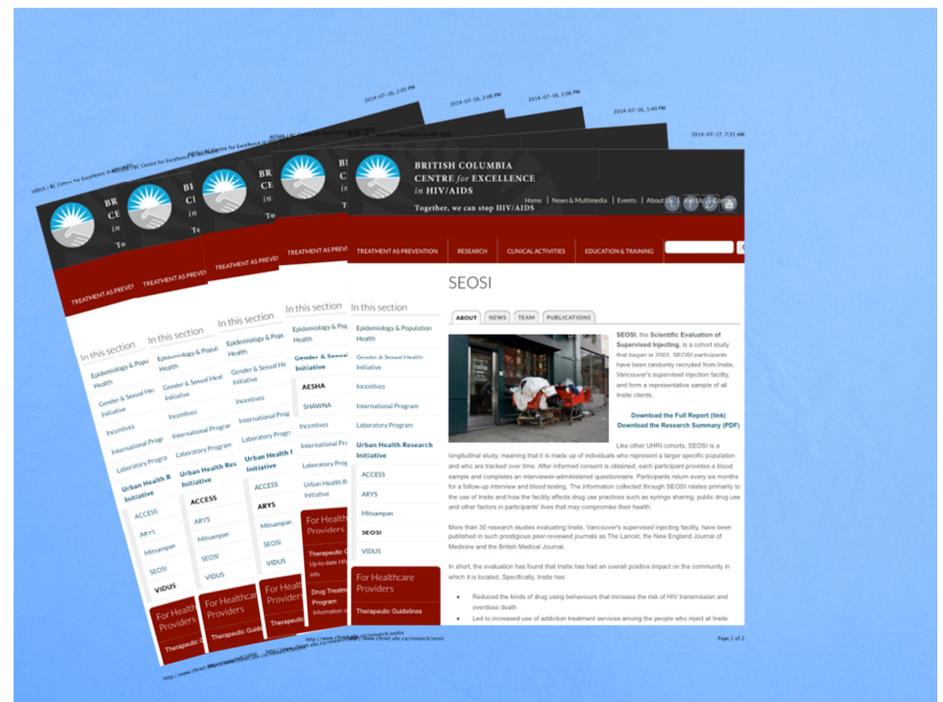
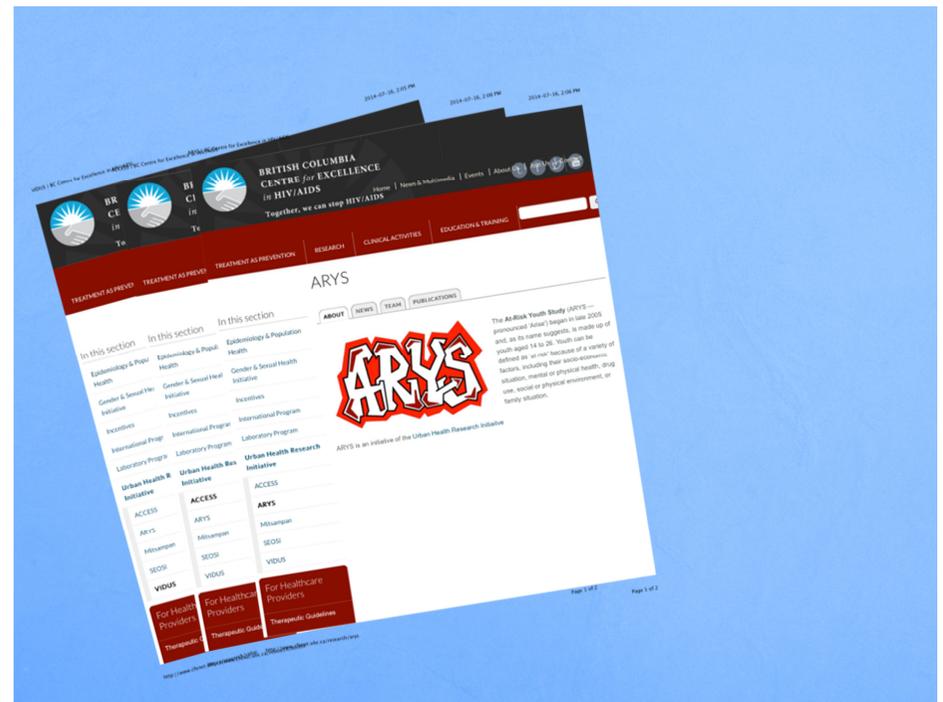
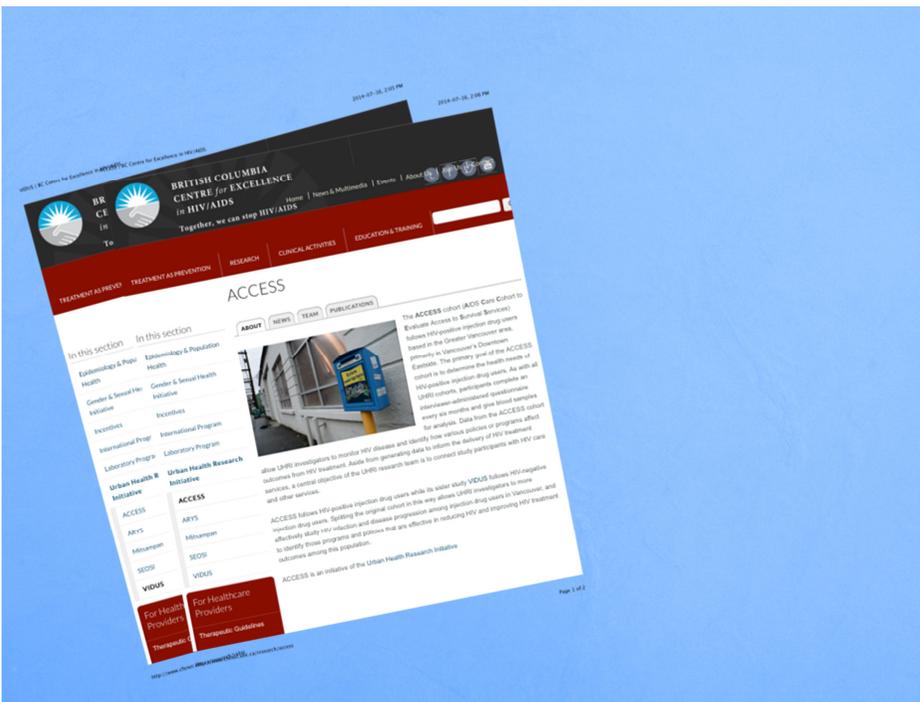
Current challenges

- * An Indigenous lens, especially a positive Indigenous perspective, is critical.
- * Indigenous health determinants are key.
- * Need to deal with stigma:
 - * Eroding our autonomy and right to health
 - * Lateral violence
- * Wholistic solutions - within the person, within the family, within the community, within the environment.
- * How do we leverage our successes?
- * How do we step up the pace?

Current challenges

- * HIV/AIDS research:
 - * Does not reflect OCAP/OCAS, MEPA
 - * Indigeneity often buried within, added on, or derived without an Indigenous lens

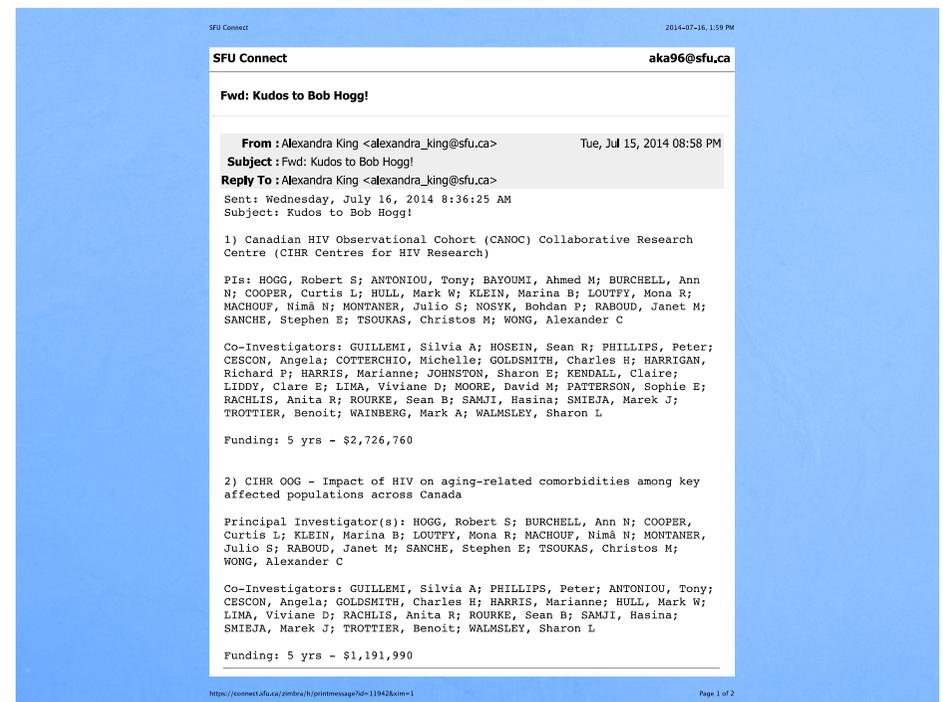






- All important studies, focusing on groups with increased vulnerabilities to HIV/AIDS (e.g., IDUs, at-risk youth, sex trade work)
- High-quality, high-powered studies, most featuring bloodwork (CD4, VL, HCV, ...) and questionnaire (1-1.5 hour interviews) every 6 months
- Both cross-sectional and longitudinal analysis
- Key vulnerabilities ... but up to 30% of participants of these studies are Indigenous people.
- Indigeneity serves as a foundational vulnerability ... and yet, Indigeneity is buried within key populations ... and these studies

- Known sub-optimal HIV care and treatment outcomes for Indigenous peoples, and complex issues of stigma, racism, poverty, gender, institutional and geographic barriers negatively impacting our sexual health and HIV care experiences.
- Where is the Indigenous study?
- Cross-sectional and longitudinal analysis
- Ideally multiple countries
- Indigenous lens as fundamental analysis, with sub-group analysis as needed
- Ability to consider drivers, gaps, programs/services/policies in specific locations and over time



Future directions

- * Need Indigenous-derived solutions
 - * Strengths-based, wholistic
 - * Indigenous leadership and direction
 - * Positive brothers and sisters
 - * Elders, Healers, Knowledge Keepers
 - * Community
 - * Health professionals
 - * Research done in a good way
- * Allies



Norval Morrisseau

(14 Mar 1932 - 04 Dec 2007)

- * *Copper Thunderbird*
- * ᑕᑦᑭᑦᑲᑦᑲᑦᑲᑦᑲᑦᑲᑦ
- * Anishinaabe (Ojibwa), Sand Point FN
- * Picasso of the North | *Indian Group of Seven*
- * Art Gallery of Newport, RI (1968)
- * Galerie St-Paul, St-Paul de Vence (1969)
- * Member of the *Order of Canada* (1979)
- * Grand Shaman of the Ojibwa (1986)
- * Holder of Eagle Feather, AFN (1995)
- * Solo exhibition at the *National Gallery of Canada* (2006)
- * Lifetime National Aboriginal Achievement Award, *Indspire* (2008, posthumous)

