Thursday, November 24, 2005 – 1:30 p.m.

Examining Vulnerable Populations Through Community-Based Research

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UNDERSTANDING HIV VULNERABILITY AMONG MIGRANT LGBT YOUTH: THE YOUTH MIGRATION PROJECT

Robb Travers [1]; Carol-Anne O'Brien [2];
1-Ontario HIV Treatment Network; 2-School of Social Work, Ryerson University;

Plain Language Summary: Toronto is a magnet for LGBT migrants from across Canada and from other parts of the world and increasing numbers of youth are drawn to the city with the hope of living a life relatively free of discrimination. Funding from Health Canada and the Wellesley Central Health Corporation allowed us to form a unique community-based research collaborative that came together in response to community concern about HIV vulnerability among new migrant LGBT youth.

Objectives: Our objectives were twofold - the first was to assess the social determinants of HIV vulnerability among migrant LGBT youth and to offer community, policy and programming recommendations that would address them. The second objective was to create a community-based research project that would enhance the abilities and capacities of our diverse partners to effect change to improve quality of life for migrant LGBT youth in Toronto.

Methods: Using qualitative methods, we conducted focus groups and depth-interviews with 100 youth and key informants focusing on migration experiences, policy and programming gaps, and suggestions for reform. We also developed and implemented a knowledge transfer strategy that prioritized 'how community members mobilize and use knowledge in their work'.

Results: LGBT migrant youth leave their home communities for many reasons including escaping violence and discrimination and seeking community. Most find themselves ill-equipped to cope with the demands and expectations of a large, complex and expensive urban centre such as Toronto. Poverty, discrimination in and out of Toronto's gay community, alcohol and drug use, involvement in the sex trade, and exploitation, heighten risk for HIV particularly among trans youth, 2-Spirit youth, refugee and new immigrant youth, and homeless youth. Our strategy for change has included a successful community forum, the production of numerous 'fact sheets' and presentation slides, as well as conference presentations and papers.

Conclusions: Community-based research is a valuable tool for effecting change, in this case, in the lives of migrant LGBT youth. The capacities for conducting collaborative work that can lead to change were significantly enhanced because we utilized a knowledge transfer strategy that began with the ways in which knowledge is used in the realm of community work.

Contact Information: Robb Travers, Tel: 416-642-6486 x311, Email: rtravers@ohtn.on.ca

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HIV/AIDS STIGMA, DENIAL, FEAR, AND DISCRIMINATION: EXPERIENCES AND RESPONSES OF PEOPLE FROM AFRICAN AND CARIBBEAN COMMUNITIES LIVING IN TORONTO

Erica Lawson [1]; Fauzia Gardezi [1]; Liviana Calzavara [1,2]; Ted Myers [1]; Winston Husbands [3]; Esther Tharao [2,3]; Anna Pancham [4]; Sylvia Adebajo [1]; Darien Taylor [5]; Clemon George & Stigma Study Team [6]; Frank McGee [7]; Robert Remis [2]; Edith Wambayi [8]; Dennis Willms [9];
1-HIV Social, Behavioural, and Epidemiological Studies Unit, Faculty of Medicine, University of Toronto; 2-Department of Public Health Sciences, Faculty of Medicine, University of Toronto; 3-African and Caribbean Council on HIV/AIDS in Ontario; 4-Toronto Public Health; 5-Canadian AIDS Treatment Information Exchange; 6-St. Michael's Hospital; 7-AIDS Bureau, Ministry of Health and Long Term Care; 8-Health and Life Promotion Research Consultancy; 9-Department of Anthropology, McMaster University and CLEAR Unit;

Plain Language Summary: This presentation focuses on how African and Caribbean people living with HIV rely on community support in their daily lives. Results indicate that people living with HIV carefully negotiate community support while minimizing the threat of social exclusion.

Objectives: To examine the role of community in the lives of HIV positive African and Caribbean people in Toronto

Methods: This study recruits HIV positive men and women and general members of the community over the age of 16 from three African (Ethiopia, Kenya, Somalia) and three Caribbean (Jamaica, Trinidad and Guyana) communities in Toronto in order to understand the role of denial, fear, stigma and discrimination associated with HIV and AIDS. This analysis focuses on the results of in-depth interviews with 25 HIV positive individuals. Participants are recruited through AIDS service organizations and community health centres. Interviews were thematically analyzed to understand how participants construct community in relation to their own identity, and how communities respond to HIV/AIDS.

Results: HIV positive participants identified poverty, language barriers, racism and lack of family networks in Canada as factors that increase dependence on community support. They expressed the desire for services and support from people of similar ethno-cultural background or racial identity. While they will access services offered through 'mainstream' organizations, many participants describe their experience as less than satisfactory. Yet, community is also identified as a moral space which constructs 'normal' sexuality and gendered identities in ways that stigmatize community members living with HIV/AIDS. As a result African and Caribbean people living with HIV go through careful negotiations over a period of time to maintain necessary community supports and to minimize the threat of social exclusion.

Conclusions: Community is a complex site with competing interests and exclusionary practices. African and Caribbean people living with HIV negotiate means for support, belonging and cultural continuity within a context in which experiences of poverty, immigration and racism, heighten the fear of exclusion from the community. Expanding HIV/AIDS education and service delivery within African and Caribbean communities is necessary. Greater efforts are required to protect people's confidentiality within their communities and to combat the association of Black communities with the origin and spread of HIV/AIDS.

Contact Information: Erica Lawson, Tel: 416-978-6928, Email: erica.lawson@utoronto.ca

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THE EXPERIENCE OF DEPRESSION AMONG ABORIGINAL PEOPLE LIVING WITH HIV

Roy Cain [1]; Randy Jackson [2]; Judy Mill [3]; Evan Collins [4]; Kevin Barlow [2];
1-School of Social Work, McMaster University, Hamilton, Canada; 2-Canadian Aboriginal AIDS Network, Ottawa, ON; 3-Faculty of Nursing, University of Alberta, Edmonton, AB; 4-Department of Psychiatry, University of Toronto, Toronto, ON;

Plain Language Summary: This presentation will describe our study-in-progress on the experience of depression among Aboriginal People Living with HIV/AIDS (APHAs). We will outline our research plan and methods, preliminary findings, and future directions for the project.

Objectives: Depression was identified as a serious concern of the members of the APHA Caucus of the Canadian Aboriginal AIDS Network, but there is little previous research that addresses this concern. Our objectives in this study are to understand: how feelings of depression are subjectively experienced by APHAs; what participants do about their feelings of depression; how participants relate their feelings of depression to their HIV infection; and, how they understand the roots of their depression.

Methods: The community-based study is based on indepth interviews with APHAs. Our participants include people at various stages of HIV infection. In partnership with our community collaborators, we are recruiting First Nations, Métis, and Inuit participants in several cities across Canada. We plan to conduct a total of about 75 interviews. Audio tapes of the interviews will be transcribed. Transcripts will be coded according to themes and theoretical categories that emerge from the data.

Results: We are still the in the early stages of data collection, but our preliminary findings suggest how feelings of depression are related to participants' experience with abuse, drinking and drug use, and social isolation. We will identify some of the complex ways that depression is related to HIV infection.

Conclusions: We will present preliminary findings from a successful community/academic partnership. Our discussion will indicate how our early findings are shaping the ongoing development of the project, and the questions it raises for our related study of service providers for APHAs.

Contact Information: Roy Cain, Tel: 905-525-9140 x27960, Email: cainr@mcmaster.ca

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DEVELOPING COMMUNITY ACTION RESEARCH ON REDUCING MENTAL HEALTH SERVICE ACCESS BARRIERS FOR IMMIGRANTS & REFUGEE PHAS

Alan Li [1,2]; **Josephine Wong** [2];
1-Regent Park Community Health Centre, Toronto, Ontario, Canada; 2-Committee for Accessible AIDS Treatment, Toronto, Canada;

Plain Language Summary: People with HIV/AIDS who are immigrants, refugees or without legal status in Canada face profound challenges that affect their mental health and wellbeing. They also suffer complex barriers in accessing mental health support and services due to a mixture of barriers related to different determinants of health related to their status as newcomer and PHA. The Committee for Accessible AIDS Treatment (CAAT) has been working with diverse stakeholders and affected PHA groups to address service access barriers since 2000. Our previous research project funded by OHTN has led to many innovative community based initiatives created to address the treatment access needs of marginalized PHAs. Through previous research and ongoing community needs assessments, mental health needs and service access issues were identified as priority for research and focus for action. In 2004, CAAT received OHTN funding to conduct literature review, program scan and full research proposal development. Adhering to principles of community based and community driven research, CAAT undertook various process to involve diverse community stakeholders to clarify challenges faced by the target populations, examine existing resources and gaps, and identify research priority and developed a full research study framework with multiple components that will aim at knowledge transfer, community capacity building and policy changes.

Objectives: The oral presentation will share experiences on the challenges and successes learned through the process of developing a community based action research study to address mental health service access barriers faced by immigrant & refugee PHAs.

Methods: The project involves extensive community development strategies to involve target communities in the guiding the research development process, including needs assessments, literature review, program scan, research priority setting and focus group consultations.

Results: This community based research development process resulted in a two phase, six component research study that will involve knowledge building and transfer from both service users and service providers, capacity building in affected communities, identification and development of best practice models, training curriculum and policy recommendation.

Conclusions: Using a community based research model, CAAT has successfully engaged multi-sectoral partners in developing an action research study aimed at reducing mental health service access barriers faced by immigrant & refugee PHAs.

Contact Information: Alan Li, Tel: 416-364-2261, Email: alanl@regentparkchc.org

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HEALTH AND HOUSING: ASSESSING THE IMPACT OF TRANSITIONAL HOUSING FOR PEOPLE LIVING WITH HIV/AIDS

Ruthann Tucker [1]; **Ligaya Byrch** [1]; **Sue Ferrier** [2]; **Lori Chambers** [3]; Robin Weir [4];
1-Fife House; 2-Institute for Work & Health; 3-York University, School of Social Work; 4-CLEAR;

Plain Language Summary: Using qualitative, one-on-one interviews we investigate the impact of transitional housing for PHAs who have lived in the up to nine month long Hastings program. The workshop will provide an overview of CBR, partnership building, preliminary research findings, and an examination of housing and the impact it has on the everyday lives of PHAs in the Canadian context. Currently, there is a derth in terms of available literature which examines supportive housing for PHAs in the Canadian context. This research is one of two ground breaking undertakings Fife House is involved with in the province of Ontario.

Objectives: 1. To increase the agency's capacity to conduct Community Based Research; 2. To develop an evaluative tool which can be utilized within the agency to evaluate all programs; 3. To inform the agency around program develop particularly as it relates to the building of a new residential site; 4. To involve PHAs through the project and learn from their everyday lived experiences.

Methods: 1. Qualitative, one-on-one, interviews with PHAs who have lived in the Hastings program since April 2000; 2. Community Based Research; 3. Utilizing the standpoint theory as developed by Dorothy Smith-learning from the everyday lived experiences of PHAs and staff of the Hastings program.

Results: 1. The program works, even if some clients return to the program several times; 2. Communal living is challenging; 3. Individual's overall health and well-being improve with stable housing.

Conclusions: Supportive housing is key to creating stability and improving the health and well-being for PHAs who have been chronically homeless.

Contact Information: Ligaya Byrch, Tel: 416-205-9888 x31, Email: lbyrch@fifehouse.org

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THE IMPACT OF ASO PRISON SERVICES ON THE QUALITY OF LIFE OF INMATES

John MacTavish [1]; Joanne McAlpine [2]; Kim Dolan [3]; Joanne Lush [4]; Peter Ford [5]; **Robin Weir** [6]; Gina Browne [6]; Jacqueline Roberts [6]; Greg Robinson [7];
1-Acting ED, HIV/AIDS Regional Services (HARS); 2-Former ED, HIV/AIDS Regional Services (HARS); 3-Acting ED, Peterborough AIDS Resource Network (PARN); 4-Former ED, Peterborough AIDS Resource Network (PARN); 5-HIV Prison Study Group, Queens University; 6-Investigator, Community Linked Evaluation AIDS Resource (CLEAR) Unit, Hamilton, ON; 7-Former Co-Director, CLEAR Unit, Hamilton, ON;

Plain Language Summary: Correctional Services Canada (CSC), two Community Based AIDS Organizations (CBAOs) and a hospital based HIV clinic initiated a collaborative effort to provide HIV/AIDS related health care and prevention education and support services for inmates infected/affected by HIV/AIDS. The objective of this study was to evaluate the services provided to inmates in terms of their satisfaction and to determine the impact of services on inmates' health related quality of life.
These two CBAOs and clinic provided HIV/AIDS services, which were rated by users as highly satisfactory, and reached those vulnerable respondents in most need of the services.

Objectives: The primary objective of this study was to measure inmates' satisfaction with the services provided by CBAO personnel and to determine the impact of these services on inmates' quality of life. Additionally, key staff at the CBAOs and CSC were invited to be interviewed to determine their perceptions of the effectiveness of the services provided.

Methods: This was a one-time survey of current users (inmates) of prison support services provided by HARS and PARN and the prison HIV clinic. Thirty-six participants were recruited from the inmate population of 8 of the 11 Ontario federal penitentiaries serviced by HARS and PARN. A structured, one hour, face to face or telephone interview was conducted to detail their satisfaction with services provided, health related quality of life, coping strategies, depression and their use of prison support services. Respondents were assembled in two groups by amount of prison support service use and compared on the above variables.

Results: High and low users of CBAO support services differed on a number of variables with high users imprisoned longer, with higher cognitive functioning and more active behavioural coping through information seeking. At the same time, high users had higher levels of depression and a pattern of more health distress. Depressed respondents tended to engage in more risk behaviours. Overall, CBAO prison support services were endorsed positively by inmates as well as CSC personnel.

Conclusions: The importance of prevention education and support services is indicated in the findings of this study particularly to those individuals with mental health issues which are highly related to risk behaviour.

Contact Information: Robin Weir, Tel: 905-525-9140 x22293, Email: weirr@mcmaster.ca

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Basic Science

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THE ROLE OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)-SPECIFIC CD4+ HELP IN ACUTE HIV INFECTION: CONSIDERATION FOR VACCINE DEVELOPMENT AND THERAPY

Brad R. Jones [1]; Feng Yun Yue [2]; Colin M. Kovacs [3,4]; Ruqaya Mohamed [1]; Kelly MacDonald [1,5,6]; Mario A. Ostrowski [2,3];
1-Department of Immunology, University of Toronto; 2-Clinical Sciences Division, University of Toronto; 3-St. Michael's Hospital, University of Toronto; 4-Canadian Immunodeficiency Research Collaborative; 5-Department of Medicine, University of Toronto; 6-Department of Microbiology, Mount Sinai Hospital;

Plain Language Summary: The human immune system exhibits the capacity to control HIV-1 infection. In most individuals this protection eventually fails; however there are persons for whom it persists. Understanding how this control is achieved will aid in the development of vaccines and therapies. The presence of a type of immune cell, called a CD4+ T-cell, that responds to virus by producing a certain signal, called IL-2, is associated with control of HIV-1. The present study further characterizes this part of the immune system in recent infection.

Objectives: An HIV-specific CD4+ T-cells response which produces IL-2 in response to virus is associated with protection. We will identify, and characterize, IL-2 inducing CD4+ T cell epitopes from acute HIV-1 infection. The sequences of these epitopes will be monitored over time to determine if IL-2 responses exert a selective pressure that influences viral variation.

Methods: HIV-1-p55-specific, IL-2 secreting CD4+ T-cells were cloned from an acute seroconverter and their epitope/HLA specificities were defined. Immunogenic responses to these epitopes, as well as to p55, in peripheral blood were monitored over-time using intracellular cytokine staining. Circulating viruses from plasma were sequenced by a limiting-dilution methodology at corresponding time-points to look for evidence of immune escape by sequence variation. Custom peptides representing the variant epitopes detected by this method were tested against the original clones for their ability to induce a response.

Results: Three p55-specific IL-2-secreting CD4+ T-cell clones were isolated from an acute seroconverter. The epitopes targeted by these clones initially induced responses dominated by IL-2 production. While responses to these epitopes largely failed within one year post-infection, this could not be solely attributed to the emergence of viral quasi-species with intra-epitope mutations conferring escape. While one escape mutant was confirmed, the frequency of the mutation remained constant at 10% over a 2 month period, providing no indication of selection. Conspicuously positioned mutations flanking all three epitopes were ubiquitously established within 4 months post-infection. These mutations may confer escape by interfering with epitope processing. This is currently being investigated.

Conclusions: The loss of an IL-2 response to HIV-1 antigens that characteristically accompanies disease progression was observed in OM214. This failure could not be attributed solely to viral evasion of immune responses through the fixation of escape mutations within targeted epitopes. Examining the responses of these clones to autologous p55 from both early and late stages of infection will shed light on whether the observed intra-epitope and flanking mutations represent means of escape.

Contact Information: Brad Jones, Tel: 647-296-9457, Email: brad.jones@utoronto.ca

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DRUG RESISTANT HIV1 STRAINS RETAIN SENSITIVITY TO INHIBITION BY THE GLYCOLIPID, ANALOGUE ADAMANTYLGB3

Darinka Sakac [1]; Nicole Lund [1]; Beth Binnington [2]; Murugesapillai Mylvaganum [2]; Don Branch [1]; **Cliff Lingwood** [2];
1-Canadian Blood Services, Toronto, Ontario M5G 2M1 Canada; 2-Research Institute, Hospital for Sick Children, Toronto, Ontario M5G 1X8 Canada;

Plain Language Summary: The HIV virus shows a very high rate of mutation and because of this has the ability to develop resistance to many different protocols used to treat the infection clinically. Glycolipids are sugar lipid conjugates found in the outer membrane of lymphoid target cells. The soluble derivative of one glycolipid, Gb3, involved in HIV fusion, is an effective inhibitor of HIV strains, irrespective of cellular infection preference. We have found that sensitivity to adamantylGb3 inhibition of infection is fully retained in clinical HIV strains which have developed resistance to anti-retrovirals, protease inhibitors or fusion inhibitors. This provides a new approach to treating HIV and its drug resistant forms

Objectives: To determine whether the development of resistance by HIV to current clinical management strategies results in any cross-resistance to adamantylGb3 inhibition of HIV infection in vitro.

Methods: Multiple drug resistant HIV strains were obtained from NIH and propagated in fresh activated PBMCs while aliquots were pretreated ± adamantylGb3 for 30 minutes at room temperature prior to infection of PHA-IL2 activated PBMCs. Infection was monitored as a function of time using a p24 ELISA

Results: HIV-1 strains resistant to protease inhibitors, saquinovir, anti-reverse transcriptase nucleosides and the T20 fusion inhibitor, infuvertide, were found to be equally sensitive as laboratory and wild-type clinical strains to inhibition of infection by adamantylGb3.

Conclusions: Development of resistance to drugs in current clinical practice should have no impact on clinical susceptibility to adamantylGb3 inhibition of infection in vivo. AdamantylGb3 would therefore provide an additional treatment recourse if resistance to other HIV treatments becomes apparent.

Contact Information: Clifford Lingwood, Tel: 416-813-5998, Email: cling@sickkids.ca

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EFFECT OF GP120 AND CYTOKINES ON THE FUNCTIONAL EXPRESSION OF P-GLYCOPROTEIN (P-GP), AN ATP BINDING CASSETTE (ABC) EFFLUX DRUG TRANSPORTER, IN CULTURED GLIAL CELLS

Patrick Ronaldson [1]; Manisha Ramaswamy [1]; Reina Bendayan [1];
1-Department of Pharmaceutical Sciences, Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, ON, Canada;

Plain Language Summary: P-gp is a drug efflux pump known to export anti-HIV drugs from the brain, thereby reducing their ability to treat HIV-1 encephalitis (HIVE), a neurodegenerative condition. The goal of this study is to determine if toxic substances present in the brain during HIVE [i.e., HIV-1 viral coat proteins (gp120), cytokines (TNF-α IL-1β, IL-6)] can alter P-gp expression and activity. We observed that gp120 decreased both P-gp expression and activity in astrocytes, a type of brain cell infected by HIV-1. We also demonstrated that P-gp protein levels were increased by TNF-α, decreased by IL-6, and not changed by IL-1β. These observations imply that anti-HIV drug distribution and permeation in the brain may be altered during HIVE.

Objectives: Human immunodeficiency virus type 1 (HIV-1) infection of the brain may result in HIV-1 encephalitis (HIVE), a chronic neurodegenerative condition (Kaul & Lipton, 2004). The pathological events associated with HIVE (i.e., production/secretion of cytokines) may be modelled in vitro by the exposure of cultured glial cells to the HIV-1 viral envelope protein gp120. An obstacle to the pharmacological treatment of HIVE may be the expression of ABC efflux drug transporters (i.e., P-gp) known to export anti-viral drugs from brain cellular targets of HIV-1 infection (i.e., astrocytes, microglia) (Lee et al. 2001; Ronaldson et al. 2004a, 2004b). At present, it is unknown if HIV-1 infection of glial cells and/or cells triggered with HIV-1 viral proteins can alter the molecular expression and functional activity of efflux drug transporters such as P-gp. Although cytokines (i.e., TNF-α IL-1β, IL-6) have been shown to modify P-gp expression in other tissues (Fernandez et al. 2004), their role in altering brain expression of P-gp during HIVE is unknown. The goal of this project is to investigate the effect of gp120 and cytokine treatment on P-gp expression in primary cultures of rat astrocytes.

Methods: Primary cultures of rat astrocytes were incubated for the desired time (i.e., 6 h, 12 h, 24 h) in the presence of 1.0 nM gp120 or recombinant cytokines (i.e., 0.3-0.5 ng/ml and 10 ng/ml TNF-α, IL-1β, IL-6). Gene and protein expression were determined by RT-PCR and ELISA/immunoblotting analysis respectively. Transport properties of radiolabelled digoxin, an established P-gp substrate, were investigated at 37°C in monolayers of cultured rat astrocytes.

Results: Semiquantitative RT-PCR and ELISA analyses demonstrated increased expression of TNF-α, IL-1β, and IL-6 mRNA and protein in rat astrocyte cultures treated with 1.0 nM gp120. Following exposure to gp120, P-gp protein expression was decreased up to 4.7-fold in primary cultures of rat astrocytes. Digoxin accumulation (1 h) was significantly enhanced (1.8-fold) in gp120 treated astrocytes compared to control. Furthermore, digoxin accumulation was not increased by P-gp inhibitors (i.e., PSC833, GF120918) in gp120 triggered cells, suggesting a loss of P-gp mediated transport activity. Cytokine treatment showed that P-gp protein expression was increased by TNF-α (2.9-fold) and not significantly altered by IL-1β. In contrast, P-gp protein expression was significantly decreased (8.9-fold) in the presence of IL-6.

Conclusions: Gp120 and cytokine treatment can modulate the functional expression of P-gp in cultured rat astrocytes suggesting that complex drug-transporter interactions may occur during the pathological response associated with HIVE.

Supported by the Ontario HIV Treatment Network and the Canadian Institute of Health Research.

Contact Information: Patrick Ronaldson, Tel: 416-946-7523, Email: ptronaldson@sympatico.ca

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UP-REGULATION OF A PROTEIN TYROSINE PHOSPHATASE IS LIKELY RESPONSIBLE FOR INHIBITION OF HIV-1 INTEGRATION BY ACTIVATION OF THE VPAC2 NEUROENDOCRINE RECEPTOR

Payman B.Bokaei [1,4]; Ma Xue-Zhong [2,3]; Darinka Sakac [4]; Donald R. Branch [1,2,3,4];
1-Institute of Medical Science, University of Toronto; 2-Department of Medicine, University of Toronto; 3-Division of Cell and Molecular Biology, Toronto General Research Institute; 4-Research and Development, Canadian Blood Services, Toronto, Canada;

Plain Language Summary: We have shown that stimulation of a cellular protein, VPAC2, with three specific activators inhibits HIV-1 infection. These activators cause a biochemical signal within the cell resulting in a block of the insertion of the virus into the cell's DNA; thereby inhibiting the ability of the virus to reproduce itself; thus, stopping infection. This finding may lead to novel treatments for HIV/AIDS.

Objectives: We have previously shown that stimulation of the VPAC2 receptor results in inhibition of productive infection with HIV-1. We hypothesized that VPAC2 agonists induce a signalling pathway(s) that targets an early stage of the HIV-1 life cycle, which ultimately inhibits the HIV-1 infection

Methods: VPAC2 agonists were examined for ability to inhibit HIV-1 infection of Jurkat and human primary mononuclear cells. Viral entry was monitored by PCR of viral cDNA. 2-LTR circles were examined using nested PCR of U3 and U5 regions of viral cDNA. Viral integration also used nested PCR, based on designed primers for virus LTR and ALU repeats of the host DNA. PCR products were hybridized to a radioactive LTR probe to identify a single fragment of predicted size. Western immunoblot used anti-phosphotyrosine (pTyr) to determine the total pTyr-containing proteins (pTyr) with and without VPAC2 agonist stimulation. Malachite green assays were used for protein tyrosine phosphatase (PTP) activity.

Results: Daily treatment with physiologic concentrations (10-9M) of VPAC2 agonists caused up to 90% inhibition of X4 or R5 infections. VPAC2 agonists did not affect HIV-1 entry or reverse transcription of viral RNA; however, proviral integration was blocked as was 2-LTR circle formation. Initial studies of the signalling pathway(s) responsible for the block in HIV-1 integration suggested a decrease in pTyr-containing proteins following stimulation of VPAC2. This observation was supported by tests showing an increase in PTP activity following stimulation of VPAC2.

Conclusions: These results show that VPAC2-specific agonists are strong inhibitors of HIV-1 infection; mediated by an induced block in the ability of the viral cDNA to integrate into the host genome. Initial results suggest a specific signaling pathway resulting in increased PTP activity is responsible for the inhibitory effect on HIV-1 infection following VPAC2 stimulation. Elucidation of the PTP and the signaling pathway responsible for the block in ability of HIV-1 cDNA to integrate may provide insight into the pathogenesis of the virus as well as lead to novel future treatments for HIV/AIDS.

Contact Information: Payman Bokaei, Tel: 416-313-4678, Email: payman.baradar@utoronto.ca

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THE ROLE OF IL-7 RECEPTOR ALPHA (CD127) IN DETERMINING THE FATE OF HUMAN CD8+ T-CELLS IN HEALTH AND HIV DISEASE

Angela M. Crawley [1]; Jonathan B. Angel [1,2,3];
1-Ottawa Health Research Institute, Ottawa, Canada; 2-Department of Biochemistry, Microbiology and Immunology, University of Ottawa; 3-Division of Infectious Diseases, Ottawa Hospital-General Campus, Ottawa, Canada;

Plain Language Summary: Infection with HIV is initially controlled by a strong CD8+ T-cell response; however progressive disease results in a loss of CD8+ T-cell cytotoxic activity. In untreated patients, the expression of interleukin (IL)-7 receptor alpha (CD127) on CD8+ T-cells is decreased while antiretroviral therapy restores expression to near normal levels. In this laboratory, it has recently been described that IL-7 down-regulates CD127 expression on isolated CD8+ T-cells. Critical for T-cell development and a signal for cell survival, IL-7 is part of a family of gamma-chain receptor-sharing cytokines (IL-2, -4, -9, -15, -21) that maintain naïve and memory T-cell populations. Differences in CD8+ T-cell responsiveness to cytokines and other stimuli may be associated with the retention of surface CD127 expression.

Objectives: To describe the regulation of CD127 surface protein expression, protein secretion and mRNA production by isolated CD8+ T-cells treated with IL-2, -4, -15 and -21. To determine the cell division potentials of isolated CD8+CD127+ and CD8+CD127- T-cells activated with mitogen or T-cell receptor stimuli and cytokine.

Methods: Isolated human CD8+ T-cells were cultured with IL-2, -4, -15 or -21 and the expression of CD127 was evaluated by flow cytometry. A competitive CD127-specific ELISA was used to quantify secreted CD127 in culture supernatants. Total CD127 (membrane and secreted forms) and membrane-only mRNA will be quantified by real-time PCR. The cell survival and proliferation potentials of isolated CD8+CD127+ and CD8+CD127- T-cells treated with cytokine and mitogen or T-cell receptor stimuli are being evaluated by flow cytometry using carboxyfluorescein diacetate succinimidyl ester (CFSE) and this assay will identify naïve or effector cells and memory cells.

Results: Most of the gamma-chain receptor cytokines significantly down-regulated CD127 expression on isolated CD8+ T-cells. Similar to IL-7, CD127 secretion is induced by IL-4 and IL-15. Preliminary results indicate qualitative differences between activated CD8+CD127+ and CD8+CD127- T-cells treated with cytokines. Specifically, the division potentials of CD8CD127- T-cells are significantly greater than CD8CD127+ T-cells. The quantification of CD127 mRNA transcripts is in progress.

Conclusions: These results confirm that gamma-chain receptor cytokines share another common function; CD127 downregulation. The cell division potentials of CD8CD127+ and CD8CD127- T-cells in response to cytokines and mitogen suggest cell fate differences between the subsets. Future experiments will investigate these parameters in HIV-infected individuals to identify disease-associated aberrations of T-cell response.

Contact Information: Angela M. Crawley, Tel: 613-737-8673, Email: acrawley@ohri.ca

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FUNCTIONAL SIMIAN IMMUNODEFICIENCY VIRUS GAG-SPECIFIC CD8+ INTRAEPITHELIAL LYMPHOCYTES IN THE MUCOSAE OF SIVMAC251- OR SIMIAN–HUMAN IMMUNODEFICIENCY VIRUS KU2-INFECTED MACAQUES

Liljana Stevceva [1]; Marcin Moniuszko [1]; Xavier Alvarez [2]; Andrew A. Lackner [2]; Genoveffa Franchini [1];
1- Basic Research Laboratory, National Cancer Institute, Bethesda, MD, USA; 2-Tulane National Primate Research Center, Covington, LA, USA;

Plain Language Summary: Intraepithelial lymphocytes (IEL's) are cytotoxic lymphocytes located in the mucosal layers in between epithelial cells. As such, they represent the first line of cellular defense against infectious agents that enter the body through mucosal layers of the gut and vagina such as the HIV virus. In this study we used experimental model of the HIV infection induced in monkeys with the Simian Immunodeficiency Virus (SIV). We isolated IEL's from infected and immunized monkeys and looked if they were specific for the SIV virus. We found that there is a good number of cytotoxic IEL's specific for the SIV virus, that they are activated (ready to kill) and that they produce IFN gamma cytokine in response to SIV antigens. Furthermore, we found that these cells could be induced by immunization. These findings may have an important role in designing HIV vaccines.

Objectives: The objectives of this study was to assess if there are cytotoxic, SIV-specific IEL lymphocytes in the mucosa of SIV infected monkeys and whether they are activated and functional. We aimed at looking if it is possible to induce SIV-specific cytotoxic IEL's by immunization.

Methods: IEL's were isolated from vaginal and rectal mucosa and SIV-specific IEL's were visualized by direct staining with tetrameric complexes for the immunodominant SIV epitope Gag. They were than analyzed by staining for the CD69 activation marker and IFN gamma production in response to Gag. In situ staining in tissues for T cell markers and the Gag tetramer was also done.

Results: Here, by using the tetramer technology, we were able to detect the presence of SIV Gag-specific lymphocytes in the intraepithelial compartment of intestinal and vaginal mucosae on isolated IELs and in tissues of SIVmac251- or simian–human immunodeficiency virus (SHIV) KU2-infected macaques. Furthermore, we demonstrated that these cells are activated and able to secrete IFN-g. In addition, CD3+CD8+ Gag181 – 189 CM9-positive IELs were found in the cervicovaginal and intestinal tissues of macaques immunized before SIVmac251 challenge (536, 582, and 815).

Conclusions: According to this study, it would appear that cytotoxic SIV-specific IEL's exist in the mucosa of SIV infected macaques. More importantly, these cells can be induced by immunization. This is likely to be important in increasing the capacity of the vaginal and rectal mucosal barrier to kill the virus and thus prevent the spread of the infection.

Contact Information: Liljana Stevceva, Tel: 443-538-4674, Email: liljana@hotmail.com

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Prevention Challenges Among MSM

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WHO ARE TORONTO BAREBACKERS?

Barry D, Adam [1]; Winston Husbands [2]; James Murray [3]; John Maxwell [2]; Chris Lau [2];
1-University of Windsor; 2-AIDS Committee of Toronto; 3-Ministry of Health and Long-Term Care;

Plain Language Summary: This study reports on the characteristics and beliefs of a sizeable set of MSM who have largely abandoned safer sex practices.

Objectives: To identify circuits, networks, and sites of vulnerability to HIV transmission among MSM as a foundation for developing specific, culturally-appropriate messaging that speaks to the needs of diverse sets of MSM.

Methods: Survey of 947 men attending Toronto Pride 2005.

Results: Half of the study participants who report having unprotected anal sex with a casual male partner during the last six months also report being part of the bareback scene and/or cruising bareback websites. This set of men shows a distinct profile compared to men who practise safe sex and men whose unprotected sex is unrelated to barebacking. They are more likely to be found in certain gay venues, "sexually adventurous" as defined by recent Australian researchers, involved with crystal meth and "party and play" scenes, and HIV-positive. They also confirm, as a whole, findings from previous qualitative research (published in Culture, Health and Sexuality 7 (4)) that they have a distinctive set of beliefs that justifies these practices grounded in a notion of the rational, responsible, masculine actor.

Conclusions: While many of these men may be successfully sero-sorting and thus not transmitting HIV, they nevertheless represent a very significant proportion of unprotected sex occurring among MSM and present a particular prevention challenge as their specific beliefs must be engaged if change is to occur.

Contact Information: Barry Adam, Tel: 519-253-3000 x 3497, Email: adam@uwindsor.ca

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DELAYED APPLICATION OF CONDOMS IN A COMMUNITY SAMPLE OF GAY AND BISEXUAL MEN: MISPERCEPTIONS OF SAFER SEX?

Ted Myers [1]; Dan Allman [1,2]; Liviana Calzavara [1]; Robert Remis [1]; John Maxwell [3];
1-HIV Social, Behavioural and Epidemiological Studies Unit, Dept. of Public Health Sciences, University of Toronto; 2-Centre for Research on Families and Relationships, The University of Edinburgh; 3-AIDS Committee of Toronto;

Plain Language Summary: In 2003, Calzavara et al identified delayed application as a source of HIV transmission. This paper describes the prevalence of delayed condom application within a large community of gay and bisexual men in Ontario, and compares the correlates of delayed condom application among men who only report safer sexual practices and by those who report unprotected anal intercourse.

Objectives: To describe the prevalence of delayed condom application and to compare the correlates of delayed condom application among men who only report safer sexual practices and by those who report unprotected anal intercourse.

Methods: An anonymous, self-completed cross-sectional survey was conducted with 5,080 gay and bisexual men in 13 Ontario communities. Men were asked about the frequency with which they delayed application of condoms for insertive anal sex in the previous 12 months. Among men who reported delayed application, a series of logistic regression analyses were conducted to examine the characteristics of men who delayed application and also reported that they always had safer sex.

Results: Among men who responded to questions on both delayed insertive application and sexual behaviour, 52.4% (n=1,465/2,868) reported at least one episode of delayed application. Of these 27.8% (n=407) reported safer sexual practices only, whereas 72.2% (n=1,058) reported unprotected anal sex. Independent predictors of delayed application among those reporting only safer practices were: Toronto men vs others (OR=1.7, p<.05), income <$10k vs $10k-$49k (OR=1.7, p<.02); income >$49k vs $10k-$49k (OR=1.73 p<.05); non-gay identity vs gay (OR=3.7, p<.008), gay bar attendance (OR=1.5, p<.01); bathhouse attendance (OR=1.3, p<.06); more sex partners (OR=3.0 p<.0001); regular partner (OR=0.3, p<.0001); casual partners (OR=2.3, p<.0001), having had an HIV test (OR=1.5, p<.03); ever having Chlamydia(OR=1.5, p<.05), and no cocaine or crack use(OR=0.7, p<.03).

Conclusions: Calzavara et al (2003) identified delayed application as a possible source of HIV transmission. This practice appears to be prevalent across a spectrum of the gay community, with a substantial number of men reporting safer sexual practices but also engaging in this risk behaviour. While this analysis suggests that many of the variables commonly associated with other forms of sexual risk behaviour are the same, no association was found with age, race, language, education and multiple drug use. The complex patterns of behaviour and social interactions that influence risk behaviour within the gay community require continued examination.

Contact Information: Ted Myers, Tel: 416-927-0231, Email: ted.myers@utoronto.ca

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NO DECLINE IN INCIDENCE DENSITY AMONG MEN WHO HAVE SEX WITH MEN UNDERGOING REPEAT DIAGNOSTIC TESTING IN ONTARIO

Ann Burchell [1]; Liviana Calzavara [1,2]; Robert Remis [1,2]; Ted Myers [1,2]; Carol Swantee [3]; Carol Major [3]; Paul Corey [2]; Janet Raboud [2]; & the Polaris Study Team [1];
1-HIV Social, Behavioural and Epidemiological Studies Unit, Faculty of Medicine, University of Toronto; 2-Department of Public Health Sciences, University of Toronto; 3-HIV Laboratory, Ontario Ministry of Health and Long-Term Care;

Plain Language Summary: The rate of new HIV infections among men who report sex with men is not decreasing. The authors reviewed HIV-antibody test records among men who tested more than once in 1993-2003. The rate declined in the early to mid-1990s. The rate then increased after 1996, and did not go down, even in 2000-2003. Monitoring the number of new infections is important to understand the status of the epidemic in Ontario.

Objectives: To describe HIV incidence among men who have sex with men (MSM) undergoing repeat testing in Ontario in 1993-2003, and determine whether rates have declined since 1999.

Methods: Men using voluntary, diagnostic HIV testing at least twice and reporting a risk factor of "sex with men" (but no injection drug use) were identified by computerized and manual record linkage as of 31/12/2004. In the 1993-2003 period, 603 seroconverters and 17,361 repeat negative testers contributed 60,469 person years (PY) of observation. Incidence density was calculated by apportioning seroconversions across calendar years. 95% confidence intervals (CI) were calculated using exact methods. Poisson regression was used to test for independent effects of year, geographic region, and age; results are reported as adjusted rate ratios (RRadj). Calendar time trends were compared between the pre- and post-HAART eras (defined as 1993-1996 and 1997-2003).

Results: The overall incidence rate in 1993-2003 was 0.97 per 100PY. Incidence declined in the pre-HAART era (RRadj=0.82 per year) and climbed again post-HAART (RRadj=1.09 per year). Compared to 1999, incidence declined in years 2000-2001 but increased again in 2002-2003. However, no incidence estimate in 2000-2003 was statistically significantly lower than in 1999. Incidence rates were highest among men aged 15-39, then declined thereafter. Incidence was highest in Toronto, followed by Ottawa, and was lowest in other regions of Ontario.

Conclusions: The observed incidence estimates in 2000-2003 are evidence that rates have not declined since 1999 despite intensified prevention efforts initiated in 2000 in response to detected increases. Incidence may be continuing to increase over time, or rates may have stabilized at a higher rate since the lowest point observed in 1996.

Contact Information: Ann Burchell, Tel: 613-526-1425, Email: ann.burchell@utoronto.ca

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ON THE IMPORTANCE OF COMMUNITY IN HIV RISK TAKING BEHAVIOUR

Clemon George [1];
1-Neurobehavioural Research Unit, St. Michael's Hospital;

Plain Language Summary: Epidemiologist seldom adopt the principles of community based research in designing studies and as such, the contextual reasoning for HIV risk behaviour cannot be used as a guide to measure and interpret behaviour. Further, studies of the determinants of high risk behaviour for HIV seldom take into account participant's social and ethnic culture, further reducing their utility for prevention initiatives. The present work illustrates this gap and identifies different ways of improving epidemiological studies.

Objectives: To describe HIV risk taking behaviour in groups of individuals within their social, cultural and ethnic framework.

Methods: The design of three epidemiological studies of sexual behaviour were critically analyzed to appraise how the social, ethnic and other cultural context of participants were measured, and to illustrate how community based approach could have been used to improve these measurements. The first study was a cross sectional study of sexual behaviour among high school students, conducted in Dominica in 2000. The second study looked at the changes in high risk sexual behaviour among men who have sex with men (MSM) in Montreal (1997 – 2003). This study was based on the Omega Cohort, a longitudinal study to determine the incidence of HIV in Montreal and psychosocial, demographic and other factors associated with seroconversion to HIV. The third study characterised the sexual and other high risk behaviour of 4 groups of MSM – White born in Canada, White born outside of Canada, other race/ethnicity born in Canada, other race/ethnicity born outside of Canada - based on data gathered from the Omega Cohort and the Vanguard Project, a similar study to the Omega study but carried out in Vancouver.

Results: The individual studies themselves are important for HIV prevention activities in their target populations: the first study showed that early sexual activity and inconsistent condom use were frequent among girls; the second study showed that the proportion of men practising unprotected anal intercourse (UAI) increased between 1997 - 2003; the third study showed that White men who were born outside of Canada were more likely to practice UAI while traveling outside of their home province. However, the utility of these studies would have been greater for prevention work in the target communities had these communities been involved in all stages of the research process.

Conclusions: For highly stigmatized diseases or behaviour, it is important to involve members of the target communities in all aspects of the research process. It is imperative that scientific investigators adopt a community based approach in carrying out epidemiological studies so that more appropriate and meaningful results can be obtained, leading to more effective intervention strategies.

Contact Information: Clemon George, Tel: 416-864-6060 x6493, Email: georgec@smh.toronto.on.ca

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LYMPHOGRANULOMA VENEREUM (LGV) IN TORONTO

Camille Achonu [1]; Effie Gournis [1]; Jo-Ann Ackery [1]; Rhonda Kropp [2]; Barbara Yaffe [1]; **Rita Shahin** [1];
1-Communicable Disease Control, Toronto Public Health (TPH) ; 2-Sexual Health and STI Section, Public Health Agency of Canada;

Plain Language Summary: Lymphogranuloma venereum (LGV) is a systemic sexually transmitted infection caused by infection with Chlamydia trachomatis serotypes L-1, L-2 and L-3. LGV is endemic to parts of Africa, Southeast Asia, Central and South America and the Caribbean and only rarely seen in North America. In 2003, an outbreak of LGV linked to a new variant, L2b, was reported among men who have sex with men (MSM) in the Netherlands. Cases have since been reported in several European and North American cities. Enhanced surveillance for LGV carried out by the Public Health Agency of Canada (PHAC) found that the majority of cases identified in Canada have been from Toronto. Toronto's LGV cases are males who are primarily Caucasian, MSM, most likely to be coinfected with HIV and commonly report symptoms of proctitis and inguinal lymphadenopathy.

Objectives: To review all reported LGV cases in Toronto and describe demographic, risk factor and clinical presentation trends.

Methods: Key epidemiological information was collected by public health investigators from confirmed and probable LGV cases reported to Toronto Public Health. Data collected as of October 3, 2005 was abstracted and analyzed using descriptive methods.

Results: As of October 2005, 29 probable and confirmed cases of LGV were reported in Toronto. Although identified retrospectively, the first case reported symptoms as early as November 2001. All identified LGV cases have been males ranging in age from 24 to 53 years and appear to be epidemiologically unlinked to each other and unrelated to travel. The majority of LGV cases (96%) reported sexual contact with other males. The most frequently reported concurrent sexually transmitted infection was HIV, which was reported in 83% of LGV cases with a known HIV history. The most commonly reported symptoms included proctitis (86%) and inguinal lymphadenopathy (52%)

Conclusions: The epidemiology of the Toronto cluster of LGV is similar to the cases linked to the outbreak in Netherlands. The high proportion of HIV coinfections is of concern for the following reasons: HIV transmission may be facilitated by the presence of lesions associated with LGV, risky behaviours among MSM may be putting them at risk for acquiring HIV and LGV and finally, HIV positive individuals may be particularly susceptible to acquiring and presenting with LGV. Further research is needed to investigate possible reasons for the high rate of HIV and LGV coinfection.

Contact Information: Camille Achonu, Tel: 416-392-7423, Email: cachonu@toronto.ca

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INTERVIEW ACCOUNTS OF HIV SEXUAL RISK EVENTS AMONG GAY AND BISEXUAL MEN ENROLLED IN THE POLARIS HIV SEROCONVERSION STUDY (2004-2005)

Dennis Haubrich [1]; Karen Ryder [2]; Domenico Calla [2]; Liviana Calzavara [2,3]; Ted Myers [2,3]; & the Polaris Study Team [2];
1-School of Social Work, Faculty of Community Services, Ryerson University; 2-HIV Social, Behavioural and Epidemiological Studies Unit, Faculty of Medicine, University of Toronto; 3-Department of Public Health Sciences, University of Toronto;

Plain Language Summary: This study identifies and describes HIV sexual risk events among gay and bisexual men. Forty-eight gay and bisexual men (7 HIV-positive and 41 HIV-negative) were interviewed about a self-identified HIV risk event. HIV-positive men were asked about the risk event that they believe led to their seroconversion, while HIV-negative men were asked about the risk event that led to their most recent HIV test. Psychological and social factors play a combined role in HIV sexual risk-taking.

Objectives: To identify and describe self-reported HIV sexual risk events among gay and bisexual men in the Polaris cohort.

Methods: Polaris is a longitudinal, open-cohort study of recent seroconverters and HIV-negative controls in Ontario. Participants are recruited through Ontario's HIV diagnostic testing database, physicians, community organizations and media. Data are drawn from face-to-face, semi-structured interviews with 48 gay and bisexual men (7 HIV-positive and 41 HIV-negative) who enrolled in the study between January 2004 and July 2005. HIV-positive men were asked about the risk event that they believe led to their seroconversion, while HIV-negative men were asked about the risk event that led to their most recent HIV test. Interviews were audio-taped and transcribed verbatim. Interview texts were analyzed to identify significant themes.

Results: Accounts of HIV sexual risk events identify a confluence of factors, some of which are common to both HIV-positive and HIV-negative gay and bisexual men. Use of substances, particularly crystal meth, ecstasy, cocaine and alcohol were reported as influencing their sexual risk behaviour, most commonly, unprotected anal sex. Relational factors such as starting a new relationship, validation of assumed monogamy, and HIV risk in the context of anonymous sex were also reported. In addition, non-consensual condom removal during anal sex and non-disclosure of HIV-positive status by a sexual partner were identified as reasons for testing. Improper condom use and condom failure were also reported. A number of negative participants reported routine HIV testing without an associated risk event. Among the HIV-negative participants, those in serodiscordant relationships also reported testing routinely 'just in case'.

Conclusions: The psychosocial influences on HIV sexual risk behaviour continue to pose multiple challenges to HIV education and prevention programs. In particular, our findings highlight the need to further understand the co-occurrence and mediating influences of recreational substance use on sexual risk behaviour. Research also needs to identify and explicate non-consensual sexual behaviours.

Contact Information: Dennis Haubrich, Tel: 416-979-5000 x6219, Email: djhaubrich@sympatico.ca

Thursday, November 24, 2005 – 1:30 p.m.

Knowledge Transfer And Exchange (KTE): Research Results In Action

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HOW WELL DID THE ASSUMPTIONS CAMPAIGN REACH MSM AT RISK?

Barry D. Adam [1]; Winston Husbands [2]; James Murray [3]; **John Maxwell** [2]; Chris Lau [2];
1-University of Windsor; 2-AIDS Committee of Toronto; 3-Ministry of Health and Long-Term Care;

Plain Language Summary: This study reports on the responses of MSM to the national Assumptions Campaign (aka How Do You Know What You Know?) launched in Toronto in the summer of 2004.

Objectives: To identify the reach and effectiveness of this HIV prevention campaign among men attending Toronto Pride.

Methods: Survey of 947 men attending Toronto Pride 2005.

Results: Almost half (48.7%) reported seeing a poster, ad, booklet, or condom pack from the How Do You Know That You Know campaign. Higher rates of awareness were reported among those with the Toronto postal codes of M4X-M5B. Of those who had seen the campaign, 87.4% found if effective in raising awareness about safer sex and 70.0% indicated that it made them think about or question assumptions they were making about a partner's sero-status. Only those reporting heterosexual identity and no male partners in the last six months, and those with a US postal code, showed low awareness of the campaign. Participants in the bareback scene were somewhat less likely to find the campaign effective. Those reporting unprotected anal sex with a casual partner were significantly more likely to report having questioned their own assumptions following the campaign, as were those reporting having given in to unprotected sex because of depression and those who perceive that a lot of guys have no desire to use condoms in sex. Follow-up booklets called Condoms Unwrapped and Getting Together had weak penetration in the community with only 11% and 7.2% respectively having seen them.

Conclusions: Assessment of the Assumptions Campaign shows considerable openness and support among gay and bisexual men to HIV prevention campaigns tailored to them. While most of the Pride sample did not have unprotected sex in any case, those more at risk were also more likely to report having attended to and absorbed the intended message but their behaviour is not clearly impacted. The follow-up program in the ensuing year has had a low profile, and participants in the bareback scene require alternative approaches.

Contact Information: Barry Adam, Tel: 519-253-3000 x3497, Email: adam@uwindsor.ca

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FUN & GAMES': USING GAMES AS AN EDUCATIONAL TOOL FOR CANADIAN HIV-POSITIVE YOUTH

Sarah Flicker [3]; Stanley Read [1]; Alex McClelland [4]; Harvey Skinner [3]; Darien Taylor [2]; Eudice Goldberg [5]; Tiffany Veinot [2]; Alison Buchan [5];
1-Department of Infectious Diseases, The Hospital for Sick Children; 2-Canadian AIDS Treatment Information Exchange (CATIE); 3-Department of Public Health Sciences, University of Toronto ; 4-Positive Youth Outreach, AIDS Committee of Toronto; 5-Division of Adolescent Medicine, The Hospital for Sick Children;

Plain Language Summary: Research shows that HIV-positive youth are not accessing health and social services and are therefore lacking the information they need to stay healthy and make informed treatment decisions. In response, the Positive Youth Research Project was initiated by HIV-positive youth who identified a need for on-line educational resources. The design and development of an interactive website has been driven by HIV-positive youth in collaboration with academic researchers and community agencies. Health issues, concerns and information gathered from individual interviews and focus groups is uniquely presented and disseminated in the format of 'choose your own adventure' games and quizzes. This format gives youth an opportunity to problem solve and make decisions about real-life issues while also learning about treatment and other options. These games are effective educational tools for youth.

Objectives: Globally, half of all new HIV infections occur among young people. As of June 30, 2003, there have been 721 positive HIV tests in Canada among youth aged 15 to 19 years, and 13,083 among individuals aged 20 to 29 years. Despite this growth, there is a profound lack of resources for HIV-positive youth in Canada. Research also shows that more youth today than ever before are using the Internet. The Positive Youth Project was developed in response to the voiced need HIV-positive youth to have a website containing relevant youth-friendly information and resources. The goal of the site is to engage youth in educational materials through games and quizzes.

Methods: The Positive Youth Research Project uses a community-based participatory research model to address the needs of positive youth in Canada. A stakeholder group of positive youth and supporting professionals collaboratively developed the research design, instruments and protocol for the research and intervention. Focus groups were held across the country with a broad spectrum of HIV-positive youth to identify relevant issues and the best ways of exploring/presenting data. In total 40 youth, and 23 service providers were interviewed individually and in group formats. A national advisory group met regularly to generate themes from the data and guide the development of the site.

Results: Many youth identified the need for information about HIV/AIDS in a readable, engaging format. Youth wanted help understanding treatment decisions, making choices about pregnancy and general health issues. A number of complexities surfaced around making health decisions and youth asked for tools to guide them through decision making and reduce social isolation. In response, games and quizzes were created to address their concerns. All the graphics were designed by HIV-positive youth and content vetted through youth and service providers.

Conclusions: The creation of the www.livepositive.ca website has allowed youth to express themselves and communicate with one another to reduce the stigma and isolation that often surrounds HIV-positive youth. Youth have appreciated the opportunity to engage and discuss their treatment decisions through a fun and non-threatening medium. Further, this partnership assisted in developing trust between HIV-positive youth and AIDS serving organizations. As a result, HIV-positive youth have started to feel connected to each other, have access to information and feel they have a voice in the decision-making processes. They may therefore be more likely to avail themselves of more appropriate health and social services.

Contact Information: Alison Buchan, Tel: 516-813-8859, Email: alison.buchan@sickkids.ca

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KNOWLEDGE TRANSLATION: AN ABORIGINAL PERSPECTIVE ON RESEARCH DISSEMINATION

Yvon Allard [1]; **Renee Masching** [1]; Randy Jackson [1];
1-Canadian Aboriginal AIDS Network, Ottawa, Ontario, Canada;

Plain Language Summary: The Canadian Aboriginal AIDS Network (CAAN) has taken a leadership role regarding HIV/AIDS related research and Aboriginal Peoples. This abstract highlights the concept of Knowledge Translation and what this means when doing research with the Aboriginal community.

Objectives: To share CAAN's understanding of Knowledge Translation and describe the strategies advocated by CAAN to disseminate and implement research findings.

Methods: In 2005, CAAN established a research unit in recognition of the leadership role the organization is taking regarding HIV/AIDS research related to Aboriginal Peoples. The unit includes two Research Technical Assistants who will take a lead in developing resources regarding the research process. One such resource is the discussion paper "How can CAAN effectively engage in Knowledge Translation regarding HIV/AIDS issues with Canadian Aboriginal Peoples." Drawing upon literature, community input and research experience, the discussion paper addresses the principles of Aboriginal ownership, control, access and possession and the priority for Knowledge Translation that shows greater sensitivity to Aboriginal communities' perceptions, needs, unique circumstances and knowledge. The paradigm of Knowledge Translation is explored in the context of the history of research on Aboriginal Peoples and working with Aboriginal communities to conduct research that is meaningful and leads to change.

Results: Historically, research has been part of colonization. For research to be meaningful in the present it must incorporate Knowledge Translation and be designed from conception to lead to change. This paper identifies expectations and strategies, with examples, of CAAN's approach to research and specifically Knowledge Translation.

Conclusions: Knowledge Translation activities are crucial for advancements in decreasing the burden of illness among Aboriginal Peoples. For this to occur there must be interest and expertise to support the translation of research findings into program initiatives and to rigorously evaluate these programs. As a part of its commitment to shape both practice and policy, CAAN actively supports knowledge translation and exchange strategies designed to ensure that new knowledge is shared and used to improve care, treatment and prevention services, and to shape policy.

Contact Information: Renee Masching, Tel: 902-405-6343, Email: reneem@caan.ca

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"OPERATION HAIRSPRAY" – AN INNOVATIVE COMMUNITY APPROACH TO HIV/AIDS EDUCATION

Zhaida Uddin [1]; **Orhan Hassan** [2]; **Zaineb Al-Kutoby** [3]; **Claudette Fagan** [4];
1-Multicultural Health Team, Ottawa Public Health, Ottawa, Canada; 2-Healthy Sexuality and Risk Reduction Program, Ottawa Public Health, Ottawa, Canada; 3-Multicultural Health Promoter, South East Ottawa Centre for a Health Community, Ottawa, Canada; 4-Peer Volunteer, Cameo Unisex Hair Salon, Ottawa, Canada;

Plain Language Summary: Operation Hairspray is an innovative peer-led health promotion initiative, which seeks to engage African and Caribbean hairdressers and barbers as a channel to reach people from countries where HIV is endemic. In 2001, HIV infections among people from African and Caribbean countries where HIV is endemic represented a quarter of all reported HIV cases in Ottawa. This trend is not limited to Ottawa, epidemiological data show a similar pattern of increase occurring provincially and nationally. Ottawa Public Health wishes to address these issues by implementing a peer-led health promotion strategy to ensure better access to knowledge and support for members of the African and Caribbean communities.

Objectives: Increasing community capacity; increasing access/reducing barriers to health information on STI's and HIV/AIDS prevention and evaluating the effectiveness of a peer-led model as a channel to increase knowledge about HIV/AIDS prevention within the African and Caribbean communities in Ottawa.Several studies and research projects have demonstrated that the peer-led model is an effective health promotion strategy. With adults, interventions with popular opinion leaders have been proven very effective in motivating behavioural change around HIV.

Methods: Recruitment of a Project Advisory Group (PAG), consisting of at least one community member and at least one hairdresser/barber from the African or Caribbean communities, public health representatives, and an academic researcher in the field of HIV/AIDS, will monitor the development, implementation and evaluation of the initiative. Recruitment of Hairdressers and Barbers, who provide services to the African and Caribbean communities, in Ottawa. These volunteers will participate in a training to become peer educators. Hairdressers and barbers are specifically targeted for recruitment due to the nature of their work, the quality of their client interactions and their strong communication skills. Data collection tools include: Pre and post training questionnaires for Peer Educators, Log Sheets to track type and number of community contacts, Reaction sheets, Log Book. These are some examples of tools that will be used to gather both qualitative and quantitative data for analysis.

Results: To date, fifteen peer volunteers have been recruited and trained to deliver HIV/AIDS education information to their clients. Preliminary analysis of data collected on the log sheets indicates that all trained peer volunteers have been able to have between 1-61 discussions per week about HIV with their clients. More detailed analysis of data to follow.

Conclusions: Building partnership and trust within the community takes a lot of investment of time, however, once the community is on board, many doors open to provide health education information. This appears to be an effective health promotion strategy for disseminating information and raising awareness of HIV/AIDS and local services with Ottawa's African and Caribbean communities. This strategy may be applicable to other health issues and provide new avenues for identifying the health needs of communities, and planning future health services.

Contact Information: Zhaida Uddin, Tel: 613-580-2424 x20136, Email: zhaida.uddin@ottawa.ca

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CANADA'S 1ST AFRICAN AND CARIBBEAN HIV PREVENTION GUIDELINES, FOR AND BY AFRICAN AND CARIBBEAN PEOPLE: A VALUABLE TOOL FOR SERVICE PROVIDERS AND POLICY MAKERS

Llana James [1,2];
1-African and Caribbean Council on HIV/AIDS in Ontario; 2-Women's Health in Women's Hands Community Health Centre;

Plain Language Summary: African and Caribbean people living in Canada are at higher risk for HIV infection compared to other heterosexual, non injecting populations. However, service providers across Canada do not have HIV prevention guidelines specific to African and Caribbean communities living in Canada to inform and facilitate culturally relevant and appropriate service provision. The African and Caribbean HIV Prevention Guidelines address HIV prevention, testing/diagnosis and care as well as socio-behavioral issues such as stigma, discrimination and homophobia related to HIV prevention, testing/diagnosis and care specific to African and Caribbean communities living in Canada.

Objectives: The objectives of the African and Caribbean HIV Prevention Guidelines are to: 1) Increase the knowledge of service providers to enable them to work more effectively with African and Caribbean communities in relation to HIV/AIDS, 2) Increase the cultural competency of service providers who provide HIV-related and non HIV-related services to African and Caribbean communities in Canada, 3) Provide recommendations to a broad range of service providers, policy makers and funding bodies which will assist in reducing and eliminating HIV transmission among African and Caribbean people living in Canada.

Methods: A literature review was conducted to identify issues related to HIV prevention for African and Caribbean communities and identify existing HIV prevention guidelines. A working group was created to provide feedback on the structure and content of the Guidelines. Project partners that had a broad range of expertise, from the two provinces with approx. 90% of the African and Caribbean population were recruited to provide valuable input and feedback about the Guidelines. Clinical and non clinical external readers/reviewers also provided feedback.

Results: The Guidelines are in progress. To date the current version of the African and Caribbean HIV Prevention Guidelines have been deemed comprehensive.

Conclusions: The African and Caribbean HIV Prevention Guidelines are currently under development and are scheduled for release in 2006. They will be available in French and English, in print, and accessible via the internet through the Canadian HIV/AIDS Information Centre, Women's Health in Women's Hands Community Health Centre, and the African and Caribbean Council on HIV/AIDS in Ontario.

Contact Information: LLana James, Tel: 416-593-7655 x229, Email: llana@whiwh.com

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HOW OTTAWA GOT ITS "CRACK PIPES": AN INTEGRATED COMMUNITY APPROACH TO HARM REDUCTION

Lynne Leonard [1]; **Paul Lavigne** [2];
1-HIV Prevention Research Team, Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, Ontario, Canada; 2-City of Ottawa Public Health, Ottawa, Ontario, Canada.;

Plain Language Summary: This paper describes the various tasks and contacts made by the Ottawa Public Health Department in order to get approval for the city's NEP to distribute devices to smoke crack safely. In the six months since approval, more people have come to the NEP for service and 1,597 kits and over 17,000 glass stems have been distributed in order to reduce the harm associated with drug use. Ottawa's successful experience may be useful in assisting other NEPs or AIDS Service Organizations to mount their own safer inhalation equipment distribution programme.

Objectives: Ottawa has the highest provincial levels of HIV prevalence and incidence among women and men who inject drugs and levels of hepatitis C virus (HCV) infection among this group are among the highest in Canada. Recent international research suggests that injection drug users (IDUs) may be at increased risk of HCV infection through sharing implements to smoke crack. These findings have particular relevance to Ottawa where two community-based research projects working with Ottawa IDUs document that 75% of IDUs accessing the services of the city's needle exchange programme (NEP) also smoke crack. Although Ottawa has a well-established NEP operated by the city's Public Health Department which distributes a comprehensive array of harm reduction resources for drug users who inject, there was no distribution of resources to initiate or maintain safer crack smoking. The objective of this paper is to describe the process whereby Ottawa Public Health was able to add the distribution of safer inhalation equipment to its range of harm reduction resources.

Methods: As Ottawa has experienced, and continues to experience, significant community, political and police opposition towards its harm reduction initiatives for IDUs, mobilizing a comprehensive integrated community-based approach to lobby the Board of Health to approve the distribution of safer inhalation equipment as a component of a public health programme was essential. This multi-faceted approach involved: the institution of a consultative committee to the NEP appointed by City Council and comprising service users, community representatives and health care professionals; securing local epidemiological evidence demonstrating the enhanced HIV- and HCV-related risk profile of crack-smoking IDUs; obtaining authoritative legal advice on the status of inhalation equipment; mobilizing community support through personal or written representation from more than 30 community members, health care professionals and professionals from jurisdictions already distributing safer inhalation kits; and briefing civic health professionals.

Results: City Council, as the Board of Health, approved the programme after intense debate and Ottawa Public Health commenced distribution of safer inhalation equipment through its fixed and mobile NEP site and through street outreach April 1 2005 and later through 11 partner agencies. The NEP experienced a 140% increase in service encounters one month post-implementation and six months post-implementation (September 2005) 1,597 safer inhalation kits and over 17,000 glass stems have been distributed.

Conclusions: A multi-stakeholder, multi-faceted community-based approach can be successful despite significant opposition in scaling-up interventions to reduce the harm associated with drug use.

Contact Information: Lynne Leonard, Tel: 613-562-5800 x8286, Email: lleonard@uottawa.ca

Friday, November 25, 2005 – 2:00 p.m.

Basic Science II

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A COMPARISON OF HIV-1 DRUG SUSCEPTIBILITY INFORMATION AS PROVIDED BY TWO PHENOTYPIC DRUG RESISTANCE TESTING ASSAYS

Margriet Van Houtte [1]; Gaston Picchio [2]; Koen Van Der Borght [1]; Theresa Pattery [1]; Pierre Lecocq [1]; Lee Bacheler [3];
1-Virco BVBA, Mechelen, Belgium; 2-Virco Lab, Inc. Raritan, NJ, USA; 3-Virco Lab, Inc. Durham, NC, USA;

Plain Language Summary: A direct comparison was made between antiviral drug resistance results obtained with two phenotypic assays, virco®TYPE HIV-1 (Virco, Mechelen, Belgium) and PhenoSense™ (Monogram Biosciences, Inc., South San Francisco, CA, USA), using genotype and phenotype data downloaded from the Stanford HIV-1 Database. The correlation between the results of the two assays, as well as the level of concordance in the susceptibility calls, indicate excellent agreement between phenotypic resistance assessed by both assays. Despite the fact that virco®TYPE HIV-1 and PhenoSense™ use different approaches to obtain phenotypic information, this study shows that both assays provide, on most occasions, similar interpretations of resistance across the drugs investigated.

Objectives: There are currently four commercially available assays in the United States capable of providing phenotypic information on susceptibility of HIV-1 to antiretroviral drugs. However, very limited comparative data on their performance exists. Phenotypic information available in Stanford's database provides a unique opportunity to investigate how some of these assays compare. The objective was to compare fold-change (FC) values and resistance calls obtained with the PhenoSense™ (PS) and the virco®TYPE (VT) HIV-1 assays using phenotypic and genotypic information available in Stanford's database.

Methods: PS-derived phenotypic susceptibility data (fold-change in IC50) for which genotypic information was also available was retrieved from Stanford's database. A predicted phenotype using VT HIV-1 was obtained for each genotype. Sequences with amino acids labeled Z or X or exhibiting amino acid mixtures at positions known to be associated with resistance to the drug under analysis were excluded. Only those drugs for which >150 samples were available were included in the analysis. Measured (PS) and predicted (VT) fold-changes were compared using Pearson's correlation coefficient. Susceptibility levels were interpreted using the assay-specific clinical cut-off values (CCO) for those drugs for which both assays report them (lamivudine, didanosine, stavudine, indinavir/r and lopinavir) and using the assay-specific biological cut-off values (BCO) for the other drugs. The lower CCO in the VT report was used for the comparisons. Levels of agreement in resistance calls were calculated.

Results: Between 183 and 501 samples were available in Stanford's database for comparison for all antiretroviral drugs, except tenofovir and atazanavir. Therefore, these two drugs were excluded from the study. Comparisons of measured and predicted FC values yielded correlation coefficients ranging from 0.87 to 0.98 for NRTIs, 0.85 to 0.91 for NNRTIs and 0.82 to 0.91 for PIs ($p<0.001$). Agreement in resistance calls between the two assays was 87.2% (lamivudine), 79.1% (didanosine), 89% (stavudine), 84.3% (indinavir/r) and 89.1% (lopinavir) based on CCOs, and 92.3% (zidovudine), 89.8% (abacavir), 92.9% (nevirapine), 92.5% (delavirdine), 95.4% (efavirenz), 91.9% (indinavir), 94.8% (ritonavir), 92.2% (nelfinavir), 91.2% (saquinavir) and 88.1% (amprenavir) based on BCOs.

Conclusions: Despite the fact that PhenoSense™ and virco®TYPE HIV-1 use different approaches to obtain phenotypic information, this study suggests that both assays correlate well and they provide, on most occasions, similar interpretations of resistance across the drugs investigated.

Contact Information: Margriet Van Houtte, Tel: 32-15-401-243, Email: mvhoutte@vrcbe.jnj.com

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PRECLINICAL EVALUATION OF A UNIVERSAL HIV THERAPEUTIC VACCINE

David Anderson [1]; Andrei Ogrel [1]; Jose Torres [1]; **Francisco Diaz-Mitoma** [1,2];
1-Variation Biotechnologies Inc., CHEO Research Institute, Ottawa, Ontario, Canada; 2-Children's Hospital of Eastern Ontario, Ottawa, Ontario, Canada;

Plain Language Summary: This study evaluated a novel therapeutic HIV vaccine candidate in cynomolgus macaques. The vaccine was designed to elicit a broad immune response including cellular and humoral immunity directed against multiple subtypes and variants of HIV-1. The results show the tremendous potential of this approach.

Objectives: We have evaluated a novel vaccine strategy that targets only antigenically variable regions of HIV-1, with the belief that these represent areas in which the virus is susceptible to immune recognition and elimination.

Methods: Our candidate HIV vaccine contains no conserved epitopes. We have synthesized and evaluated the immunogenicity of a peptide-based vaccine that contains a total of 176 lipidated and non-lipidated peptide variants that represent 7 antigenically variable regions of the Env and Gag proteins of HIV-1. Six cynomolgus macaques were vaccinated 5 times with the vaccine in Montanide ISA-51 adjuvant with no adverse effects.

Results: All animals had cellular immunity to naturally processed viral antigens. 3/6 animals had T helper cell responses to Env proteins from multiple, divergent subtypes of HIV-1 (B, C, and E); two additional animals recognized multiple distinct subtype B variants of HIV-1. All animals had CD8+ T cells, measured both by intracellular IFN-□ staining and ELISPOT, that recognized naturally processed epitopes delivered by vaccinia constructs encoding Env and Env/Gag/Pol proteins from multiple, divergent subtypes of HIV (A, B, C, D, E. and F). A subpopulation of HIV-specific IFN-□+ and perforin+ cytotoxic CD4+ T cells were also detected by flow cytometry in 4/6 animals. Mucosal immunity (Env-specific IgA responses in saliva) was detected in 3/6 animals. Noteworthy was the ability of sera from one of these three animals to neutralize multiple, primary, T cell tropic isolates of HIV-1 (30% of the isolates tested). Finally, vaccination of HLA A*0201 transgenic mice with the vaccine was efficacious against challenge with a recombinant vaccina vector expressing Gag/Pol/Env proteins from a clade E isolate of HIV-1.

Conclusions: This vaccine approach differs starkly from current vaccine strategies that target conserved epitopes to achieve cross-subtype immunological recognition of HIV-1. It represents a promising new approach to development of vaccines against antigenically variable viruses such as HIV, Influenza, and HCV.

Contact Information: Francisco Diaz-Mitoma, Tel: 613-737-7600 x2736, Email: abuckley@variationbiotech.com

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CORRELATES OF VIRAL SHEDDING IN HIV-1/HSV-2 CO-INFECTED WOMEN

Sameer Kassim [1]; Phillipe El-Helou [2,3]; Lynn Kelleher [3]; Marek Smieja [1,3]; Fiona Smaill [1,3]; **Charu Kaushic**;
1-Department of Pathology and Molecular Medicine, McMaster University, Hamilton, Ontario; 2-Department of Medicine, McMaster University, Hamilton, Ontario; 3-3Special Immunology Services Clinic, Hamilton Health Sciences Center, Hamilton, Ontario;

Plain Language Summary: Studies show that in patients infected with both HIV-1 and HSV-2, each virus has an affect on the infection caused by the other. We want to establish a local group of HIV/HSV-2 co-infected women where we can study the interaction between these two viral infections. We will enroll co-infected women and take cervical washes over a period of 4-8 weeks. Both viruses will be measured in the genital secretions to determine how much of each type of virus is being shed during the menstrual cycle in these women. More viral shedding implies increased risk of transmitting the virus. This type of research that will help provide much needed information regarding co-factors for increased transmission.

Objectives: HSV-2 is one of the most common STI and the most common cause of genital ulcers. It has been linked to increased susceptibility to HIV-1. Studies also suggest that the reciprocal interaction, where HIV-1 affects susceptibility and transmission of HSV-2, is also important. While there is significant body of evidence showing the effect of each virus on increased risk and clinical course of the other, factors that influence their interactions are less clear We have initiated a study to establish a local cohort of HIV-1/HSV-2 co-infected women to examine the effect of these factors on the shedding of both viruses in the genital secretions.

Methods: Approval for the study was obtained from the local Human Research Ethics Board. Approximately 150 women coming to the SIS Clinic for treatment of HIV-1 will be recruited. Initially, women are asked to participate in a cross-sectional study to determine the seroprevalence of HSV-2 in the SIS Clinic population. In the second phase, women infected only with HIV-1 and with HIV-1 and HSV-2 will be recruited (n=30 each). Genital swabs will be collected to get at least 20 data points per patient. In addition patient questionnaires will be filled.

Results: HSV-2 seropositivity will be determined by performing EIA and confirmed by immunoblot and seroprevalence among HIV-1 positive patients will be calculated with 95% confidence interval. HIV-1 RNA levels in genital secretions will be determined by Gen-Probe HIV-1 viral load Assay. HSV-2 DNA will be measured in the genital secretions by a PCR-based quantitative assay. Patterns of HSV-2 and HIV-1 shedding during different phases of the menstrual cycle will be determined in the co-infected women and compared with HIV-1 shedding alone. Baseline CVL HIV-1 viral load will be modeled by stepwise linear regression with HSV-2 status, ethnic background, anti-viral treatment, smoking and other clinical and immunological variables.

Conclusions: The results from these studies will be very important in understanding the risks for increased transmission and acquisition of HIV-1 and HSV-2 in women. Studies such as this contribute in forming recommendations for clinical intervention.

Contact Information: Charu Kaushic, Tel: 905-525-9140 x22988, Email: kaushic@mcmaster.ca

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USE OF MODIFIED U1SNRNAS TO INHIBIT HIV-1 REPLICATION

Rade Sajic [1]; Kenneth Lee [1]; Kengo Asai [1]; Alan Cochrane [1];
1-Department of Medical and Molecular Genetics, University of Toronto, Toronto, Canada;

Plain Language Summary: The rapid evolutionary rate of HIV-1 has lead to the emergence of multi-drug resistant variants, emphasizing the need for novel inhibitory methods. One such method could be based upon inhibiting viral gene expression through disruption of HIV-1 RNA processing. A means of accomplishing this goal is through use of modified U1snRNA variants that target highly conserved regions of HIV-1. We have demonstrated such U1 derivatives can be used to yield a dramatic (>95%) suppression of HIV gene expression and are currently testing the potential of this approach in virus challenge assays.

Objectives: To determine which of the identified conserved regions of the HIV-1 terminal exon is capable of inhibiting HIV-1 replication when targeted by the modified U1snRNA by preventing viral 3' end formation. To establish a suitable method of administering these modified U1snRNA constructs as a possible HIV-1 therapeutic.

Methods: To determine the possible HIV-1 regions capable of inhibiting HIV-1 replication when targeted by the modified U1snRNA, multiple sequences where tested. The complementary 10 nucleotide sequences were inserted in the 5' end of the U1snRNA and tested by determining the HIV-1 protein expression levels when cotransfected with HIV-1 virus. Human cancer cell lines were transiently transfected with portions HIV-1 provirus and the modified U1 constructs. Viral protein production was assayed by Western blot. To verify that the effects were specific to HIV-1 and to minimize any off target effects, the modified U1snRNA were further modified to abolish their original ability to form spliceosome assembly complexes. Other techniques include Northern blotting, Alkaline Phosphatase assay, and Chloramphenicol Acetyl Transferase assay.

Results: Several sequences of the tested constructs displayed substantial HIV-1 protein inhibition when inserted in the U1snRNA construct. Our studies indicate that these modified U1 constructs can be used synergistically to further inhibit the viral protein expression. The spliceosome deficient U1 construct lacking the U1A binding site maintained partial HIV-1 viral inhibitory properties while the spliceosome deficient U1 construct lacking the U1 70K binding site lost all HIV-1 inhibition. Stable cell lines expressing the modified U1 constructs inhibited HIV-1 infection by 50% (decrease viral load) when compared to cells expressing wild type U1.

Conclusions: We have determined several sequences in HIV-1 that when targeted by the modified U1snRNA inhibit viral structural protein expression by as much as 95%. Partial inhibition was maintained when the modified U1snRNA was further modified to lose spliceosome initiating ability making it a strong candidate as a therapeutic agent for HIV-1.

Contact Information: Rade Sajic, Tel: 416-978-2500, Email: rade.sajic@utoronto.ca

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INTERACTION BETWEEN FEMALE GENITAL EPITHELIAL CELLS AND SEXUALLY TRANSMITTED VIRUSES

Sherie Fernandez [1]; Amy Gillgrass [1]; Erin MacDonald [1]; **Charu Kaushic** [1];
1-Department of Pathology and Molecular Medicine, McMaster University, Hamilton, Canada;

Plain Language Summary: Our lab has utilized primary genital epithelial cultures to investigate initial viral interactions and epithelial responses to HSV-2 and HIV. Using murine primary vaginal and uterine epithelial cultures we have discovered that these cells have different interactions with HSV-2 in terms of infectivity and cytokine secretion post-infection. We are now utilizing human primary cervical and endometrial epithelial cultures to investigate how HIV is transmitted to the female genital mucosa and how genital epithelial cells (EC's) respond to HIV exposure.

Objectives: Our objective is to investigate how female genital EC's interact with sexually transmitted viruses such as HIV and HSV-2. We are interested in determining how these viruses infect the female genital mucosa. We are also interested in characterizing how genital EC's respond in terms of cytokine secretion after exposure to HSV-2 and HIV

Methods: Primary genital EC's grown on matrigel- coated cell inserts were used for infection studies. EC's grew in polarized monolayers, mimicking the in vivo environment and in some experiments were co-cultured with stromal cells isolated from the same tissues. Transepithelial electrical resistance (TEER's) was measured to indicate formation of tight junctions. Apical and basolateral supernatants were collected at several time points post infection and stored at –70°C. Supernatants were used to determine viral titers and perform cytokine analysis using the Luminex 100.

Results: Both murine and human female genital EC's were susceptible to HSV-2 infection ex-vivo. Virus was preferentially secreted via the apical surface. Murine uterine EC's with high TEER's were less susceptible to HSV-2 infection than cells with low TEER's. HSV-2 infection of uterine EC's resulted in decreased secretion of IL 6 and MCP 1. Human genital EC's cultured with PBMC's or T cell and macrophage cell lines, had detectable levels of HIV p24 in supernatants following apical exposure to HIV lab strains and infected semen. The mechanism of viral infection or transmission is currently being assessed.

Conclusions: Our female primary EC culture model has provided us with useful information regarding the susceptibility of vaginal and uterine epithelial cells to HSV-2. It has also allowed us to study the initial cytokine responses of genital EC's to HSV-2, which could have important implications for immune activation and/or pathology. We are currently using this model to investigate the mechanisms of HIV sexual transmission to the female genital mucosal, and cytokine responses.

Contact Information: Sherie Fernandez, Tel: 905-525-9140 x225, Email: fernansa@mcmaster.ca

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CELLULAR IMMUNE CONTROL OF HIV IN THE FEMALE GENITAL TRACT

Anuradha Rebbaparagada [1,2]; Bolette Bossen [2]; Anthony Sheung [2]; Christopher Pettengell [2,5]; Sherzana Sunderji [2]; Kelly MacDonald [2,4]; Anne Biringer [2,4]; Lidia Casciaro [3]; Sharon Walmsley [2,3]; Rupert Kaul [1,2,3];
1-CANVAC; 2-University of Toronto; 3-University Health Network, Toronto; 4-Mount Sinai Hospital, Toronto; 5-Oxford University, England;

Plain Language Summary: Globally, women are at a higher risk for acquiring HIV from an infected partner than men. The female genital tract (FGT) is the site for acquisition and transmission of HIV. Immune cells such as T lymphocytes and secreted immune factors (cytokines) are important components of the body's defense system against HIV infection. However very little is known about the types of immune cells or cytokines present in the FGT or how they are influenced by changes in menstrual cycle or the presence of genital tract infections. Our study aims to characterize the FGT immune milieu in HIV-uninfected women at different phases of the menstrual cycle and compare differences in FGT immunity between HIV-uninfected and infected women.

Objectives: The majority of sexual HIV transmission occurs across the mucosal genital membrane, and women are at a disproportionately higher risk for acquiring HIV from an infected partner. Innate and adaptive mucosal immune responses at the primary site of HIV infection in the female genital tract (FGT) define the FGT immune milieu and are postulated to be important determinants of HIV transmission. An improved understanding of how perturbations in the FGT immune milieu might alter HIV acquisition and transmission is crucial for designing mucosal HIV vaccines. Our study compares differences in the FGT immune milieu of HIV-infected and uninfected women, detects the immune associations of HIV shedding in the FGT and examines the influence of menstrual cycle and genital tract infections on these parameters.

Methods: Our study population included 21 HIV negative and 22 HIV positive women recruited at Mount Sinai Hospital and Toronto General Hospital, respectively. Immune cell populations in the FGT were quantified by surface staining and flow cytometry of exfoliated cells from endocervical cytobrush specimens. Proinflammatory and Th1/Th2 family cytokines and chemokines were measured in vaginal secretions with the cytokine bead array (CBA, BDBiosciences). HIV virus shedding (HIV-1 RNA) in the FGT and blood plasma was measured with the bDNA kit (Roche). The influence of hormonal fluctuations on the FGT immune milieu was examined in HIV-uninfected women by measuring endocervical populations and cytokines at various phases of the menstrual cycle.

Results: A one-way analysis of variance between HIV-uninfected and HIV-infected ARV therapy naïve women during the late follicular phase (d.10-18 of the menstrual cycle) revealed a significant reduction in CD1a+ immature dendritic cells ($P=0.046$) and increased RANTES levels ($P=0.025$) in HIV-infected women. The CBA provides a robust and reproducible assay for measuring vaginal cytokine levels; tumor necrosis factor alpha, IL10 and IL8 measurements from 2 different CBA panels were strongly correlated (Pearson correlation coefficients ($r2$) of 0.959, 0.957 and 0.973 and $p < 0.001$). RANTES level was strongly correlated with HIV-1 RNA shedding in the FGT ($r2=0.565$, $p<0.009$).

Conclusions: We have utilized robust and reproducible assays to measure endocervical cell populations and cytokines in the FGT. We will extend our characterization of the FGT mucosal immune milieu by correlating our phenotypic analysis of endocervical immune cell populations, cytokine profiles and HIV shedding with the molecular expression pattern of innate and adaptive immune factors in the FGT. These findings will be useful for defining the innate and adaptive immune determinants of HIV shedding in the FGT, and in monitoring future mucosal HIV vaccine trials.

Contact Information: Anu Rebbapragada, Tel: 416-946-7054, Email: anu.rebbapragada@utoronto.ca

Friday, November 25, 2005 – 2:00 p.m.

Clinical Epidemiology And Treatment Issues

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FAMILY PHYSICIANS PROVIDING HIV CARE IN CANADA AND ONTARIO

Dale Guenter [1]; Sarah Scott [2];
1-Department of Family Medicine, McMaster University; 2-College of Family Physicians of Canada;

Plain Language Summary: Family physicians are involved in HIV care in Canada and in Ontario. Only about a third of family physicians have patients that they know are HIV positive. A very small number provide advanced HIV care, treating and monitoring HIV and its complications. It may be possible to increase access to care by increasing the number of family physicians who are currently practicing and are willing to care for people with HIV.

Objectives: Family physicians are in short supply for all citizens of Canada, while people with HIV are increasing in number. Our goal was to use a currently available data base to assess how much family physicians are participating in HIV care in Canada and Ontario, highlighting how health services planning might proceed in the years ahead.

Methods: We carried out a secondary analysis of the College of Family Physicians of Canada's (CFPC) National Family Physician Workforce Database, which was collected in 2001. This was a self-reported, mailed questionnaire sent to all family physicians/general practitioners (FPs) in Canada. The CFPC obtained a current database of all licensed FPs from International Marketing Service (IMS)-Health. In total, 28,340 FPs in all provinces and territories were sent questionnaires over a 4-month period, February-May 2001. The 2001 NFPWS questionnaire was developed through the efforts of a working group of the Janus Project Coordinating Committee (see Acknowledgements) to assess many attributes of FP's practices. The questionnaire was distributed in French or English, according to the physician's preference as indicated in the IMS listing. Two questions were related to HIV care, one concerning the number of HIV patients, and the other concerning the level of care provided.

Results: The national response rate was 51%. Almost 30% reported having any HIV patients, with 3.5% having more than 5 patients. Among all respondents, 2.2% provided "ongoing advanced care with treatment of complications". In most cases, physicians providing advanced care had more than 5 patients with HIV, but almost 3% of those with 1-5 patients were providing advanced care. In Ontario, we estimate that 140 family physicians are providing advanced HIV care, and that 30% of these have 1-5 patients with HIV. Advanced care was more common among younger physicians and those in rural locations.

Conclusions: The majority of family physicians are not providing HIV care. Advanced care is sometimes provided by physicians with low case loads, and often by physicians in rural locations. Initiatives to increase the number of family physicians doing HIV care are needed. Understanding the reasons for not practicing care, and the continuing education and mentorship support needs is also important.

Contact Information: Dale Guenter, Tel: 905-523-6611, Email: guentd@mcmaster.ca

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ECONOMIC MEASURES OF QUALITY OF LIFE, MEDICATIONS, AND SYMPTOMS IN PEOPLE LIVING WITH HIV

Ahmed Bayoumi [1,2,3];
1-Centre for Research on Inner City Health, St. Michael's Hospital; 2-Division of General Internal Medicine, St. Michael's Hospital; 3-Departments of Medicine and Health Policy, Management, and Evaluation, University of Toronto;

Plain Language Summary: We interviewed 206 PHAs about their symptoms and measured their quality of life using economic techniques. We found that quality of life is strongly related to symptom burden but not to specific antiretroviral therapy use directly.

Objectives: Most studies of economic measures of quality of life (utilities) among Human Immunodeficiency Virus (HIV)-positive individuals predated currently used antiretroviral therapies and accompanying toxicities. We evaluated the association between antiretroviral drugs, symptoms, and utilities.

Methods: We interviewed volunteers (n=206) using a computer to illustrate tradeoffs, conduct surveys, and store data in real time. We elicited utilities using the Rating Scale (RS), Time Trade-Off (TTO), and Standard Gamble (SG) methods and symptoms using a modified HIV-specific scale. We retrieved drug information from respondents' charts.

Results: The median number of cumulative antiretrovirals used prior to the interview was 4 (interquartile range [IQR] = 3 to 5). At the time of the interview, 69 participants (34%) were not taking antiretrovirals, 61 (30%) were taking 2 or 3 drugs, 36 (18%) were taking 4 drugs, and 65 (32%) were taking 5 or more drugs. Only 6 participants (3%) reported having no symptoms. The typical respondent had 6 (IQR=4-9) mild and 2 (0-5) severe symptoms. The most common symptom was fatigue, which was mild in 96 (47%) and severe in 68 (33%). The intraclass correlation coefficient between SG and TTO scores was 0.65. There was no association between RS, SG, or TTO utility scores and the number of drugs (p for trend = 0.38, 0.68, and 0.31, respectively). There was only one statistically significant association between any utility score and a drug class: participants using a non-nucleoside reverse transcriptase inhibitor had a higher RS score than patients not using such a drug (0.56 vs. 0.47). Several symptoms were significantly associated with SG and TTO utilities, including fatigue, fevers, cognitive difficulties, diarrhea, depression, anxiety, skin problems, respiratory problems, anorexia, muscle and joint pain, sexual difficulties, and weight loss. Peripheral pain and headache were associated only with the SG; abdominal pain and physical changes related to the lipodystrophy syndrome only with the TTO. Not associated were dizziness, nausea, sleep problems, and hair loss. RS utilities were associated only with skin and respiratory problems. Each severe symptom decreased SG and TTO scores by 0.019 (95% confidence interval 0.010 to 0.028) and 0.024 (0.014 to 0.034), respectively.

Conclusions: Utility scores are determined strongly by symptom burden in HIV but not by antiretroviral therapy use. Our study suggests that SG and TTO scores are valid measures of symptom burden but RS scores are not.

Contact Information: Ahmed Bayoumi, Email: ahmed.bayoumi@utoronto.ca

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ADEQUACY OF HIV TESTING AND FOLLOW-UP IN INFANTS BORN TO HIV-INFECTED MOTHERS: A RETROSPECTIVE CHART REVIEW OF INFANTS BORN BETWEEN JANUARY 1998 AND DECEMBER 2004

Ari Bitnun [1]; Georgina MacDougall [1]; Adriana Costei [1]; Elizabeth Seary [1]; Susan King [1]; Stanley Read [1];
1-Division of Infectious Diseases, The Hospital for Sick Children, University of Toronto, Toronto, Canada;

Plain Language Summary: In this study we summarize our experience with infants of HIV-infected mothers who were born between January 1998 and December 2004 and evaluate the adequacy of HIV-testing of such infants over a 6 year period.

Objectives: Preferred routine testing for HIV infection in infants born to HIV-infected mothers in our institution consists of HIV DNA PCR at birth, 1 month and 2 months of age and HIV serology at 18 months of age. The primary objective of this study was to review the adequacy of and results of HIV testing of infants born to HIV-infected women at the Hospital for Sick Children, Toronto.

Methods: Retrospective chart review of infants of HIV-infected mothers born between January 1998 and December 2004 who were followed at the Hospital for Sick Children, Toronto. Data extracted included maternal antiretroviral therapy (ART) during pregnancy, maternal race, geographic origin of mother, gestation time, infant birth weight and infant HIV testing results including DNA PCR, culture and serology.

Results: A total of 171 infants were seen in our clinic during the study period. Of these, 116 charts have been reviewed to date (15, 11, 13, 20, 26 and 31 in 1998, 1999, 2000, 2001, 2002 and 2003, respectively). Ninety-seven women received triple ART and 12 received dual nucleoside therapy during pregnancy; 4 received no antenatal ART (data not available for 3). Mean gestational age and birth weight were 38.2±2.4 weeks and 3174±850 grams, respectively; 53% were male. HIV DNA PCR was performed in 100 infants within 1 week of birth, 108 at 1 month of age, 96 at 2 months of age and in 23 between 3 and 12 months of age. HIV serology was performed in 75 infants (65%). Testing deemed adequate to exclude HIV infection was performed in 108 cases (93%). Inadequate testing, consisting of a single HIV DNA PCR at ≥1 month of age and no serology, occurred in 6 cases (5%); these cases were either lost to follow-up (4) or were known to have left Ontario (2). None of the infants in this cohort tested positive for HIV.

Conclusions: The efficacy of current prophylactic ART strategies was confirmed by the absence of mother-to-child HIV transmission among women who received antenatal ART. The non-reactive HIV serology at 18 months in 74 of the babies suggests that 2 negative HIV DNA PCR assay results at 1 and 2 months of age are sufficient to exclude HIV infection in infants. This argues against current recommendations requiring the second negative PCR to be done at 4 to 6 months of age.

Contact Information: Ari Bitnun, Tel: 416-813-7654 x3362, Email: ari.bitnun@sickkids.ca

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DEVELOPMENT AND VALIDATION OF THE 2005 HIV TREATMENT KNOWLEDGE SCALE IN CLINICAL SAMPLES OF HIV, HEPATITIS C,AND HIV/HEPATITIS C CO-INFECTED PATIENTS

Louise Balfour [1,2,3]; John Kowal [1,2,3]; Amy Silverman [1,2,3]; George Tasca [1,3]; Gary Garber [1,2,3]; Jonathan Angel [1,2,3]; Paul MacPherson [1,2,3]; William Cameron [1,2,3];
1-Division of Infectious Diseases, Ottawa Hospital - General Campus; 2-Ottawa Health Research Institute; 3-University of Ottawa;

Plain Language Summary: The goal of this study was to develop a short, easy to use, educational HIV treatment knowledge tool that could be used to help patients, health care providers, and community groups learn more about key issues related to HIV treatment care.

Objectives: Patients' understanding of their medical conditions and treatment recommendations is an important determinant of treatment adherence across medical settings (Dunbar-Jacob & Schlenk, 1996). In the area of HIV, several knowledge scales have been developed to evaluate patients' understanding of HIV transmission, risk factors, and myths and misconceptions about this illness. No scales, however, appear to specifically assess HIV patients' understanding of more complex and specific HIV treatment issues, including optimal adherence, viral load suppression, and drug resistance. Accordingly, this study aimed to develop and validate a novel HIV treatment knowledge scale.

Methods: Twenty-four HIV treatment knowledge items were generated from extensive literature reviews and consultations with HIV experts (e.g., "HIV is cured when the HIV viral load test results becomes 'undetectable'"). Participants in this study were HIV patients (n=144), hepatitis C patients (n=92), and HIV/hepatitis C co-infected patients (n=31) recruited during regular HIV and hepatitis C clinic visits at a publicly-funded hospital in Ottawa, Canada.

Results: Results demonstrated that HIV patients and HIV/hepatitis C co-infected patients scored significantly higher than hepatitis C patients (ps<.001) in terms of HIV treatment knowledge. Treatment-experienced HIV patients also scored significantly higher than treatment-naïve HIV patients (p<.05). Significant associations were obtained between HIV treatment knowledge and time since HIV diagnosis (p<.01), level of education (p<.05), and a brief measure of general HIV knowledge (p<.001). Moreover, the proposed scale yielded adequate test-retest reliability (r=.83) and internal consistency (alpha= .89 for HIV patients).

Conclusions: In conclusion, the 2005 HIV treatment knowledge scale is a novel, psychometrically sound instrument demonstrating high levels of validity and reliability in clinical patient samples. This scale has important applications in terms of a clinical teaching tool for HIV and HIV/hepatitis C co-infected patients, as well as for other patient and non-patient groups.

Contact Information: Louise Balfour, Tel: 613-737-8037, Email: lbalfour@ottawahospital.on.ca

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AN OUTBREAK OF INFECTIOUS SYPHILIS IN TORONTO

Camille Achonu [1]; Effie Gournis [1]; Jo-Ann Ackery [1]; Nikki Whittingham [1]; Barbara Yaffe [1]; Rita Shahin [1];
1-Communicable Disease Control, Toronto Public Health (TPH);

Plain Language Summary: Since 2002, Toronto has been experiencing an outbreak of infectious syphilis. An analysis of infectious syphilis cases reported in Toronto from 2002 to 2004 was carried out to identify epidemiological factors related to the outbreak. Results indicate that males comprise the majority (96%) of cases and there is little evidence to suggest that transmission is increasing among females. The highest rates of infection was reported in males 35 to 39 and 40 to 44 years of age. The outbreak is occurring primarily among MSM and is associated with high rates of coinfection with HIV, unprotected sex, and having multiple sexual partners.

Objectives: To review all infectious syphilis cases reported from 2002 to 2004 and identify epidemiological factors related to the outbreak.

Methods: A retrospective review of all reported infectious syphilis cases from 2002 to 2004 was conducted. Demographic and risk exposure data were extracted from the provincial database (RDIS) and analyzed using descriptive methods.

Results: From 2002 to 2004, 898 infectious syphilis cases were reported to Toronto Public Health (TPH). During that time period the incidence rate doubled from 7.5 cases per 100,000 to 14.4 cases per 100,000. Males accounted for 96% of all infectious syphilis cases. The highest rate of infection was reported in males 35 to 39 years of age followed by those 40 to 44 years. The most commonly reported risk factors for acquiring syphilis were not using a condom or chemical barrier, engaging in sexual activity with a same sex partner and having multiple sexual partners. The majority of infectious syphilis cases were identified during the secondary stage of syphilis. Thirty-six percent of all reported infectious syphilis cases were coinfected with HIV. This proportion remained consistent across the 3 years. Coinfected cases were more likely to report multiple episodes of infectious syphilis and to present at a more advanced stage of disease.

Conclusions: Similar to recently reported syphilis outbreaks among MSM in other North American and European cities, the infectious syphilis outbreak in Toronto is associated with high rates of partner change, unprotected sex and high rates of coinfection with HIV. TPH has been working closely with community partners to respond to the outbreak. Interventions have included community education and outreach (through the media, bathhouses and on-line advertising), health care provider education, and enhanced surveillance.

Contact Information: Camille Achonu, Tel: 416-392-7423, Email: cachonu@toronto.ca

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CURRENT TRENDS IN HIV MOLECULAR EPIDEMIOLOGY IN CANADA: RESULTS OF THE NATIONAL SURVEILLANCE PROGRAM

Richard Pilon [1]; Neil Goedhuis [2]; Chris Archibald [2]; Gayatri Jayaraman [2]; Paul Sandstrom [1]; James Brooks [1];
1-National HIV & Retrovirology Laboratories, Public Health Agency of Canada, Ottawa; 2-Division of HIV/AIDS Epidemiology & Surveillance, Public Health Agency of Canada, Ottawa;

Plain Language Summary: During therapy, HIV can develop mutations that render the medications less effective. When an infecting virus already has mutations, treatment options are reduced from the outset. Within this cohort of first-time positive, antiretroviral-naïve (never treated) participants, 8.9% of the viruses were resistant to at least one of the drugs currently available to treat the disease.
We also found that 41% of the new infections were associated with at least one other within the cohort, suggesting a common source for these infections.

Objectives: 1. National surveillance of HIV strains and drug resistance (DR) among newly-diagnosed HIV positive Canadians. 2. Molecular epidemiology of newly-diagnosed HIV positives to evaluate transmission patterns within and between provinces participating in the national surveillance program.

Methods: Diagnostic sera from newly diagnosed, treatment-naïve, HIV positive individuals was obtained from provincial partners and analyzed for HIV subtype and genotypic DR. DR was determined using the Stanford HIV Drug Resistance Database and IAS guidelines. Phylogenetic analysis was performed by neighbor-joining analysis (K-2-P) as implemented in MEGA 3.1.

Results: Sequence data was available from 304 specimens collected between December 2003 and March 2005. Within this cohort, 8.9% had at least one primary DR mutation. The prevalence varied from 7.1% to 13.2% between provinces, as did the class of drugs affected. 1.9% of the samples contained HIV resistant to drugs from 2 or more classes. The distribution of non-B strains also varied by province (6% to 37%), with an overall prevalence of 18% (11%C, 3.6%A, 2.0% A recombinant (AE, AD, AG) and 0.3% each of D, G and H). Forty-one percent of first-time positive individuals were located in 34 provincial infection clusters consisting of up to 7 individuals. An additional seven clusters spanned two provinces, and one cluster involved individuals from 3 provinces. Two subtype A clusters were also found within one province.

Conclusions: 1. DR in Canada has remained between 6.5 and 11.5% since 2000. DR prevalence was highest (13.2%) in the province that has historically had the highest DR rates. 2. Non-B strains represent almost 40% of new infections in the province with the highest DR rates. 3. The identification of numerous transmission clusters may indicate that individuals who are unaware of their HIV status are the source of new infections. Molecular epidemiology can identify changes in the pattern of the Canadian HIV epidemic, leading to improved patient care and prevention strategies targeted to those who need it most.

Contact Information: James Brooks, Tel: 613-946-0120, Email: james_brooks@phac-aspc.gc.ca

Friday, November 25, 2005 – 2:00 p.m.

Novel And Innovative Approaches To Prevention

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INCREASING EFFECTIVENESS OF PREVENTION SERVICES: HIV EDUCATION, PREVENTION AND RISK REDUCTION MODEL FOR AFRICAN AND CARIBBEAN WOMEN

Esther Tharao [1,2,3]; **Senait Teclom** [1,3];
1-Women's Health in Women's Hands; 2-HIV Social, Behavioural and Epidemiological Studies Unit, University of Toronto; 3-African and Caribbean Council on HIV/AIDS in Ontario;

Plain Language Summary: African and Caribbean women living in Canada have a higher rate of HIV infection compared to other non-drug injecting heterosexuals. Yet existing models of HIV prevention developed to provide information and facilitate decision-making to reduce risks of HIV infection do not address the issues and factors specific to African and Caribbean women. The proposed model addresses the needs and gaps in existing models in relation to African and Caribbean women and proposes strategies to address them.

Objectives: The objectives of this abstract are to present: The process used to develop above model; Unique issues and factors incorporated in the model; and how model is structured to facilitate the ability of service providers to provide HIV education, prevention and risk reduction services that are grounded in the realities of African and Caribbean women's lives.

Methods: Information to build the model was obtained through literature review/search of existing models, research studies and reports written on issues affecting African and Caribbean women and their communities, and previous and current efforts to reduce HIV transmission and to create more effective ways of providing services for African and Caribbean women and their communities. A draft model was developed, focus tested (3 focus groups with African and Caribbean women and service providers working with them) and will be pilot tested within 9 agencies including AIDS service organizations, ethno-cultural agencies and others.

Results: a) Identified gaps were based on the lack of recognition of: The transnational nature and experience of African and Caribbean women and the global/social forces that have led to their migration to Canada (poverty/economic, education, war, natural disasters; violence based on gender, sexual orientation and harmful cultural practices; state violence, etc); the collective rather than individualistic nature of African and Caribbean cultural communities and its impact on decision making within family and community; Impact of identified factors on women's efforts/ability to prevent primary or secondary HIV transmission (ability to negotiate for safer sex); services that are not tailored to identified needs. b) Prevention strategies to deal with identified issues were developed. c) A model that incorporated issues and proposed strategies was designed and will be presented at the conference.

Conclusions: Proposed model will assist service providers to facilitate more accessible, culturally appropriate and tailor made HIV education, prevention and risk reduction services and increase the number of African and Caribbean women living in Canada accessing HIV information and prevention services.

Contact Information: Senait Teclom, Tel: 416-593-7655, Email: Senait@whiwh.com

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SOCIO-CULTURAL INFLUENCES ON HIV PREVENTIVE BEHAVIOURS OF YOUTHS OF AFRICAN NATIONALITIES IN WINDSOR, CANADA

Francisca Omorodion [1]; Kenny Gbadebo [2]; Philippine Ishak [3];
1-Department of Sociology and Anthropology, University of Windsor, Windsor, Canada; 2-Youth Connection Association, Windsor, Canada; 3-Department of Sociology and Anthropology, University of Windsor, Windsor, Canada/Windsor Women Working with Immigrant Women, Windsor, Canada;

Plain Language Summary: This study examines the sexual and reproductive behaviour of youths of African nationalities with the goal to identify the risk factors that increase their vulnerability to STIs and HIV/AIDS in Canada. Using in-depth interviews with 25 youths of diverse African nationalities in Windsor, the study shows that these youths remain misinformed on the transmission of STIs and HIV/AIDS. In addition, heritage culture and gender inequalities, as well as religiosity continue to shape the sexual and reproductive behaviour of these youths. Hearing and documenting the voices of African youths contribute to our understanding of the best ways to reach youths of ethnic minority, particularly those of African nationalities who are becoming vulnerable to HIV/AIDS in Canada.

Objectives: To examine STIs and HIV/AIDS prevention-related sexual behaviours and identify the risk factors to such infections.

Methods: Data were gathered from interviews with 25 African youths aged 18-25 years, and resident in Windsor. Data were collected using in-depth interviews and analysed using content analysis based on grounded theory.

Results: Five emerging themes arose from the interviews, awareness and concerns about STIs and HIV/AIDS; partners influence on reproductive health choices; sources of information; lack of knowledge about STIs and HIV/AIDS, and discomfort talking about sex. Fewer sex life partners were significantly associated with religiosity, and close parent-child relationship in terms of being able to communicate with parents particularly mothers. Barriers to condom use were significantly associated with gender ideologies, predisposition to heritage cultural norms and beliefs on sexuality, as well as religiosity. Gender ideologies and elements of their heritage culture tended to discourage female youths from negotiating safe sex practices, while religiosity promoted abstinence and non-use of condoms. Although there was high awareness about STIs and HIV/AIDS, a majority of the youths remained misinformed about the transmission of sexually transmitted diseases. Males tended to blame and categorize females as the primary transmitters of STIs and HIV/AIDS. Other areas of misinformation included many youths linking penal erection to semen discharge, which influence their non-use of condoms. Despite the gap in the STIs and HIV/AIDS knowledge and information among African youths, the study also noted that there is less emphasis on the use of peer educators in health promotion in Canada, particularly Windsor.

Conclusions: These findings show that HIV/AIDS prevention programs for young persons of ethnic minority in Canada need to be made culturally-sensitive and to promote the involvement of youths. The youths then called for more innovative strategies such as locating condom dispensing machines in schools, public toilets and through a proliferation of youth centers coordinated and run by youths that will increase their accessibility to condoms, information on STIs and HIV/AIDS, while linking such services to other socio-economic needs of youths such as self employment, job search and skill development.

Contact Information: Francisca Omorodion, Tel: 519-253-3000 x2203, Email: omorodif@uwindsor.ca

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HIV RISK, SYSTEMIC INEQUITIES, AND ABORIGINAL YOUTH: WIDENING THE CIRCLE FOR HIV PREVENTION PROGRAMMING

June Larkin [1]; Sarah Flicker [1,2]; **Ruth Koleszar-Green** [1,3]; Susan Mintz [1,4]; Michelle Dagnino [1,5]; Claudia Mitchell [6];
1-The Gendering Adolescent AIDS Prevention (GAAP) Project, Women and Gender Studies Institute, University of Toronto; 2-Wellesley Central Health Corporation; 3-Social Work, Ryerson University; 4-Urban Studies, University of Toronto; 5-Osgoode Law School, York University; 6-The Gendering Adolescent AIDS Prevention (GAAP) Project, Faculty of Education, McGill University;

Plain Language Summary: In this paper we discuss some of the ways Aboriginal youth understand AIDS and HIV risk. Aboriginal youth are both overrepresented in the HIV epidemic and infected at a younger age than non-Aboriginal peoples. Through an analysis of data collected in focus groups with Aboriginal youth we identify poverty, colonialism and other structural inequities as HIV risk factors for Aboriginal youth. We argue that an examination of the impact of colonialism on Aboriginal populations should be mainstreamed into prevention programming for both Aboriginal and non-Aboriginal youth. This study is part of a larger project on HIV risk and Ontario youth.

Objectives: The goals of the study were: 1) to identify HIV risk factors facing Aboriginal youth; 2) to use the data to make recommendations for HIV prevention education for both Aboriginal and non-Aboriginal youth.

Methods: We conducted four focus groups with urban Aboriginal youth in Toronto. The groups were conducted by an Aboriginal youth facilitator with strong community connections and experience in AIDS prevention education. Participants included 48 Aboriginal youth recruited from Aboriginal youth-serving agencies in downtown Toronto. A modified grounded theory approach guided the data analyses. Data were coded by a team of graduate students, the Aboriginal facilitator, and the principal investigator. The codes were entered into Nud*ist qualitative data management software.

Results: Compared to their non-Aboriginal counterparts in the larger Ontario study, Aboriginal youth were more aware of HIV/AIDS and the structural inequities that contribute to risk. They were, however, more likely to hold a fatalistic view of their future and to blame their own community for high infection rates. A finding unique to Aboriginal youth was the positive way they spoke about support systems in their community.

Conclusions: We link the discourses of self-blame in participants' comments to the negative portrayal of Aboriginal peoples in mainstream society and an emphasis on seroprevalence rates to the exclusion of social determinants of risk. We argue that incorporating the legacy of colonialism into HIV prevention programs for all youth will help to eradicate the stigma and self-blame that negatively impact on Aboriginal youth while allowing other youth populations to distance themselves from the disease.

Contact Information: June Larkin, Tel: 416-978-8282, Email: jlarkin@oise.utoronto.ca

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THE IMPACT OF SOCIAL AND RISK NETWORKS ON THE INJECTION RISK BEHAVIOURS OF MALE AND FEMALE INJECTION DRUG USERS IN TORONTO

Naushaba Degani [1,2]; Peggy Millson [1,2]; Ahmed Bayoumi [4]; Liviana Calzavara [1]; Dean Behrens [3];
1-HIV Studies Unit, University of Toronto, Toronto, Canada; 2-Institute of Medical Sciences, University of Toronto, Toronto, Canada; 3-Department of Sociology, University of Toronto, Toronto, Canada; 4-Inner City Health Research Unit, St Michael's Hospital, Toronto, Canada;

Plain Language Summary: HIV can be transmitted through the use of contaminated needles and injection equipment. Because risk occurs with other people, it is important to understand the effect relationships can have on injection drug users' (IDUs) risk behaviours and how this can differ between men and women. This study looked at the associations between injection risk behaviours and relationship characteristics. Women IDUs' risk behaviours were effected by relationship closeness and support relationships. Men, on the other hand, were effected by the number of drug contacts they had.

Objectives: This study will describe the gender differences in the associations between egocentric network characteristics (size, multiplexity and 'closeness') and injection risk behaviours (needle sharing, paraphernalia sharing and syringe mediated sharing).

Methods: A convenience sample of 150 IDU (75 males and 75 females) from the city of Toronto was interviewed in 2004. Participants were recruited through a number of sources in an effort to include a diverse cross section. Respondents were asked a series of questions about themselves, their drug use and their risk behaviours. As well, drug, sex and support networks were elicited and a series of question on each contact named were included in the interview. Analyses were conducted using SAS v8.0 and SPSS 12.0. Analyses at the participant level were logistic regression models that adjusted for confounding variables. Analysis at the level of the dyad involved hierarchical models that adjusted for data dependencies using generalized estimating equations with repeated measures corrections. All analyses were stratified by gender.

Results: The analysis of network characteristics showed significant associations with risk participation, however male and female IDUs were not affected in the same way by their networks. While female IDUs' rates of risk participation were positively associated with the inclusion of supportive, close drug relationships, male injectors were positively associated with the number of drug contacts that they had, their participation in the drug economy and their own levels of drug use. This suggests that their networks may more readily influence women who inject drugs than male injectors.

Conclusions: Relationship characteristics effect participation in risk behaviours. Network-based prevention strategies may provide an additional level of harm reduction for injection drug users, however programs should consider the differential impact of networks on male and female injection drug users and take these differences into consideration when designing effective strategies.

Contact Information: Naushaba Degani, Tel: 905-822-6991, Email: ndegani@sympatico.ca

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NEEDLE EXCHANGE PROGRAMMES WELL POSITIONED TO SCALE-UP HARM REDUCTION FOR CRACK SMOKERS

Lynne Leonard [1]; **Emily Meadows** [1]; Linda Pelude [2]; Joyce Seto [1]; Emily Medd [1];
1-HIV Prevention Research Team, Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, Ontario, Canada.; 2-Ottawa Public Health, Ottawa, Ontario, Canada.;

Plain Language Summary: The results of recent research studies show that it may be possible to catch the human immuno-deficiency virus (HIV) and the virus that causes hepatitis C infection (HCV) through sharing the various items that a person may use to smoke crack. In this study we looked at the practice of smoking crack among women and men in Ottawa who inject drugs. We interviewed 459 injection drug users (IDUs) aged 30 and under and collected samples of their saliva for testing for the presence of antibodies to the hepatitis C virus. We found that three-quarters of the IDUs we interviewed had smoked crack in the 6 months before their interview and nearly all these IDUs had shared a device to smoke crack. The results of the saliva testing showed that more IDUs who also smoked crack were living with hepatitis C infection than those IDUs who did not also smoke crack. As we found that nearly all the IDUs who also smoked crack had been to a needle exchange programme (NEP) we recommend that NEPs are a good place to help IDUs who also smoke crack to keep themselves safe from infection by talking about the risks involved in crack smoking and by distributing safer crack kits.

Objectives: Recent research evidence suggests potential HIV and hepatitis C virus (HCV) transmission risks associated with the multi-person use of crack-smoking implements. The objective of the current study was to examine crack smoking and related risk behaviors among a younger group of women and men in Ottawa who inject drugs. Ottawa has the highest provincial rates of HIV prevalence and incidence among injection drug users (IDUs) and among the highest Canadian rates of HCV prevalence among this group. Younger IDUs were considered to be less likely to be living with HIV and HCV and able to benefit from enhanced harm reduction initiatives to keep them safe from infection.

Methods: 459 active, street-recruited IDUs <30 years old consented to personal interviews and provided saliva samples for HCV testing between February 2004 and February 2005. Univariate analysis compared crack-smoking IDUs with non-crack smoking IDUs.

Results: Engagement in crack smoking among younger IDUs was high: 75% had smoked crack in the six months prior to interview, 86% in the month prior to interview. Frequency of smoking crack was also high: 46% had smoked crack more than three times a week or on a daily basis in the six months prior to interview. In terms of HIV- and HCV - related risk behaviors: 73% had shared crack-smoking implements in the six months prior to interview, 90% in the month prior to interview. HCV prevalence among crack-smoking IDUs was elevated (32.3%; 95% CI: 27.3, 37.4) compared with the prevalence among those IDUs who had never smoked crack (27.5%; 95% CI: 19.1, 35.9). A higher proportion of crack-smoking IDUs (82%) had ever accessed a needle exchange programme in any city compared with non-crack smoking IDUs (74%) $p = 0.06$.

Conclusions: Crack smoking is a common and frequent practice among younger IDUs. The multi-person use of implements to smoke crack, with documented associated HIV and HCV-related risk, is almost universal. As the vast majority of crack-smoking IDUs access NEPs, these programmes are well positioned to scale-up their harm reduction activities by implementing a safer crack-smoking initiative to include safer crack-smoking education and the distribution of safer-crack kits.

Contact Information: Lynne Leonard, Tel: 613-562-5800 x8286, Email: lleonard@uottawa.ca

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PREDICTORS OF INJECTION AND SEXUAL HIV RISK BEHAVIOURS AFTER 6 MONTHS IN A LOW THRESHOLD (HARM REDUCTION) METHADONE PROGRAMME

Peggy Millson [1,2]; Laurel Challacombe [2]; Paul Villeneuve [1]; Carol Strike [1,3,4]; Benedikt Fischer [1,4,5]; Ted Myers [1,2]; Ron Shore [6]; Shaun Hopkins [7,8];
1-Department of Public Health Sciences, University of Toronto; 2-HIV Social, Behavioural and Epidemiological Studies Unit, University of Toronto; 3-Department of Psychiatry, University of Toronto ; 4-Centre for Addiction and Mental Health, Toronto ; 5-Department of Criminology, University of Toronto ; 6-Street Health Centre, Kingston, Ontario; 7-The Works, Toronto, Ontario; 8-Toronto Dept. of Public Health;

Plain Language Summary: Injection drug use and unprotected sexual behaviour are risk factors for HIV infection. Methadone can be used to treat addiction to heroin and related drugs by providing a legal substitute which is taken orally. Low threshold methadone programs primarily aim to reduce the risk of HIV without requiring abstinence from drugs. This study included 130 participants, 90% of whom had been engaged in a risky sexual behaviour and 19% in a risky injection behaviour in the six months after entering treatment. Men, Caucasians, respondents who didn't use cocaine, and those receiving lower doses of methadone were more likely to have participated in a sexual risk behaviour. Respondents who reported risky sex with a regular partner, had poorer physical health and more psychiatric problems were more likely to have participated in an injection risk behaviour. This information can be used to identify factors which could be modified in order to help reduce the occurrence of these risk behaviours.

Objectives: To determine baseline predictors of injection and sexual HIV risk behaviours 6 months after enrollment in a harm reduction (low threshold) methadone programme.

Methods: All individuals entering two low threshold methadone programs in Ontario were invited to enroll in a prospective cohort study. Questionnaires including a set of HIV risk questions, a quality of life instrument (SF-36) and the Addiction Severity Index (ASI), were interviewer administered at baseline and every six months. An exploratory analysis using multiple logistic regression evaluated which factors were independently associated with injection and sexual risk behaviours.

Results: 130 participants were enrolled and followed to 6 months; 90% of respondents reported risky sexual behaviour and 19% reported risky injection behaviour within the six months after treatment entry. Factors significantly associated with risky sexual behaviour were: being Caucasian (OR=3.11, 95% CI 0.80-12.19), being male (OR= 4.46, 95% CI 1.03-19.32), not using cocaine use (OR=0.19, 95% CI 0.04-1.02), and lower doses of methadone in mgs (OR=0.99, CI 0.97-1.00). Factors significantly associated with risky injection behaviour were: risky sex with a regular partner (OR=2.89, 95% CI 0.97-8.61); poorer SF-36 physical composite score (OR=0.95, 95% CI0.90-0.99) and psychiatric problems (ASI; OR=5.24, CI 0.80-34.40).

Conclusions: Findings suggest that potentially modifiable factors such as poor physical and mental health predict ongoing risky injection behaviour after enrolment in a low threshold methadone program. Sexual risk behaviour is less well explained by the model, but findings suggest the importance of adequate methadone dose and targeted sex education for men to reduce risky sexual practices.

Contact Information: Peggy Millson, Tel: 416-978-5253, Email: p.millson@utoronto.ca

Friday, November 25, 2005 – 2:00 p.m.

Global And Ethical Issues: Policy And Practice

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MEDIA REPORTING OF TENOFOVIR TRIALS IN CAMBODIA AND CAMEROON

Edward Mills [1,2]; Beth Rachlis [3]; Ping Wu [4]; Elaine Wong [5]; Kumanan Wilson [6]; Sonal Singh [7];
1-Centre for International Human Rights Law, University of Oxford, UK; 2-Dept. of Clinical Epidemiology & Biostatistics, McMaster University; 3-UBC Centre for Excellence in HIV/AIDS; 4-Canadian College of Naturopathic Medicine; 5-London School of Economics; 6-Dept. of Medicine, University of Toronto; 7-Johns Hopkins Bloomberg School of Public Health;

Plain Language Summary: Two planned trials of tenofovir as a pre-exposure prophylaxis intervention to prevent HIV infection were stopped early due to activist pressures on host governments in Cambodia and Cameroon. The media represented the primary source of knowledge transfer regarding the trials. We systematically examined all media reports on the closed trials to determine consistency and characteristics of information sources. We included 30 reports on Cambodia and 14 reports on Cameroon. We found large heterogeneity of reports and few primary sources reported as source information. This study indicates that researchers should engage the media in times of controversy so as to provide accurate reports.

Objectives: Two planned trials of pre-exposure prophylaxis tenofovir in Cambodia and Cameroon to prevent HIV infection in high-risk populations were closed due to activist pressure on host country governments. The international news media contributed substantially as the primary source of knowledge transfer regarding the trials. We aimed to characterize the nature of reporting, specifically focusing on the issues identified by media reports regarding each trial.

Methods: With the aid of an information specialist, we searched 3 electronic media databases, 5 electronic medical databases and extensively searched the Internet. In addition we contacted stakeholder groups. We included media reports addressing the trial closures, the reasons for the trial closures, and who was interviewed. We extracted data using content analysis independently, in duplicate.

Results: We included 24 reports on the Cambodian trial closure and 13 reports on the Cameroon trial closure. One academic news account incorrectly reported that it was an HIV vaccine trial that closed early. The primary reasons cited for the Cambodian trial closure were: a lack of medical insurance for trial related injuries (71%); human rights considerations (71%); study protocol concerns (46%); general suspicions regarding trial location (37%) and inadequate prevention counseling (29%). The primary reasons cited for the Cameroon trial closure were: inadequate access to care for seroconverters (69%); participants not sufficiently informed of risks (69%); inadequate number of staff (46%); participants being exploited (46%) and an unethical study design (38%). Only 3/23 (13%) reports acknowledged interviewing research personnel regarding the Cambodian trial, while 4/13 (30.8%) reports interviewed researchers involved in the Cameroon trial.

Conclusions: Our review indicates that the issues addressed and validity of the media reports of these trials is highly variable. Given the potential impact of the media in formulation of health policy related to HIV, efforts are needed to effectively engage the media during periods of controversy in the HIV/AIDS epidemic.

Contact Information: Edward Mills, Tel: 416-951-8530, Email: emills@ccnm.edu

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CANADA'S INTERNATIONAL RESPONSE TO HIV/AIDS: INSIGHTS, SILENCES AND OPPORTUNITIES

Stephanie Nixon [1];
1-Department of Public Health Sciences and Collaborative Program in Bioethics, University of Toronto;

Plain Language Summary: This study investigated the Government of Canada's international response to HIV/AIDS over time – that is, what we have done outside of our borders to address the pandemic. It was concerned with ethical reasoning as well as the broader social, political and economic forces that shaped government decisions. My methods included several document reviews as well as 23 interviews with experts. The results identified new areas for advocacy, policy and research to enhance the effectiveness of our international response.

Objectives: (1) What has been the Government of Canada's international response to HIV/AIDS? (2) What are the social, political and economic forces that have shaped this response? (3) What are the ethical and ideological tensions that have underpinned the response?

Methods: The methods were empirical and non-empirical. Non-empirical aspects of the study included: (a) development of the "critical public health ethics" conceptual framework, (b) an overview of Canadian foreign policy, and (c) a document review of Canada's international response to HIV/AIDS. The empirical component of this study consisted of 23 semi-structured interviews with experts from government, civil society, private industry and the United Nations system regarding the forces that have shaped Canada's international responses and underlying ethical reasoning.

Results: Canada's international response to HIV/AIDS was found to be moderate, spotty and non-strategic. Participants also identified a tension underlying the response with public good and "doing the right thing" on one side, and Canada's economic self-interest on the other. Equally revealing were the conspicuous silences in the data that became apparent through the lens of critical public health ethics. Although almost every participant identified Canada as having a moral obligation to respond to the global HIV/AIDS pandemic, there was an absence of moral reasoning and ethical vocabulary to underpin this claim. Furthermore, few participants made the link between the role of poverty in exacerbating HIV/AIDS and Canada's connection to poverty creation through its economic and trade policies at the bilateral and multilateral levels.

Conclusions: The analysis resulted in policy, research and advocacy recommendations for Canada's international response to HIV/AIDS regarding the relative absence of discussion on poverty reduction as it links to the epidemic. This, in turn, is connected to our government's role with international monetary, trade and financial institutions, like the World Bank. The study also revealed lessons for incorporating a global mindset into the evolution of the conceptual framework of critical public health ethics.

Contact Information: Stephanie Nixon, Tel: 416-535-5577, Email: stephanie.nixon@utoronto.ca

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RANDOMIZED TRIALS STOPPED EARLY FOR HARM IN HIV/AIDS: A SYSTEMATIC SURVEY

Edward Mills [1]; Curtis Cooper [2]; Ping Wu [3]; Beth Rachlis [4]; Gordon Guyatt [1];
1-Department of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, Canada; 2-Division of Infectious Diseases, Department of Medicine, University of Ottawa; 3-Department of Epidemiology, London School of Hygiene & Tropical Medicine, London, UK; 4-UBC Centre for Excellence in HIV/AIDS, University of British Colombia;

Plain Language Summary: Randomized trials provide the strongest inferences into therapeutic effectiveness and are therefore used to evaluate the efficacy and safety of drug interventions. We examined all randomized trials stopped early due to harmful reasons. We found that most trials were not prepared to evaluate the precision of the harms and were poorly reported. It is likely that most trials that are stopped due to harmful reasons are not published. Physicians and patients should evaluate trials stopped early for harm in light of all available evidence.

Objectives: Stopping trials early due to harmful effects of the intervention requires a complex decision weighing statistical, logistical and ethical considerations. We assessed the prevalence of randomized clinical trials (RCTs) stopped early for harm in HIV/AIDS and determined the quality of reporting of methods to inform the decision to stop the trial.

Methods: Design: Systematic survey of the literature. Data sources: We searched 11 electronic databases, major conference abstract databases, contacted trialist and advocacy groups, and searched the internet. Study selection: RCTs stopped early for harm. Data extraction: Journal and year of publication, reporting of methods and funding, planned sample size, number and planning of interim analyses, stopping rules, and effect size of the harm outcomes.

Results: We found 10 RCTs stopped early for harm [Median n= 85, range 7-1227]. Most interventions (n=9) were antiviral drugs; one trial studies vitamins to prevent vertical transmission of HIV. Five studies reported a priori defined adverse events, and only 1 trial reported planned stopping guidelines. The primary harm outcomes reported across trials included toxicity, death and increased mother-to-child transmission. Two trials stopped due to sudden unanticipated adverse events (Stevens-Johnson syndrome, death and encephalopathy). The median relative risk of harm across studies is 1.49 [range 1.19-1.87]. Six studies reported the presence of a Data Safety and Monitoring Board.

Conclusions: The reporting of methods to inform the decision to stop trials for harm in this population is deficient in a variety of ways, including lack of stopping guidelines. Clinicians should interpret RCTs stopped early for harm with caution and interpret the results in light of related evidence. Trialists should improve the transparency of their decision-making regarding early stopping for harmful effects.

Contact Information: Edward Mills, Tel: 416-951-8530, Email: emills@ccnm.edu

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LIVES IN A BALANCE: ETHICAL DILEMMAS FOR INFORMED CONSENT FOR HIV TESTING IN PREGNANCY

Dale Guenter [1]; Randi Zlotnik Shaul [2]; Angela Barbara [1];
1-Department of Family Medicine, McMaster University; 2-The Hospital for Sick Children, University of Toronto;

Plain Language Summary: It is difficult to know what is the most ethical way to practice with regard to HIV testing in pregnancy. Informed consent may be valued, but is not easy to achieve, and may actually lead to more children being infected with HIV. Society must decide what ethical compromises it is willing to accept.

Objectives: HIV testing in pregnancy is treated differently in clinical practice between provinces, but also within Ontario. Our objective is to provide an ethical framework that will inform future discussion about the most appropriate approach to informed consent for pregnant women.

Methods: We will draw upon highlights from data outside Canada, and from four Ontario studies carried out by the authors: a qualitative study among 12 post-partum women about perceptions of informed consent; a survey among 300 post-partum women about prenatal testing experiences and preferences; a survey among prenatal care providers about prenatal counseling and testing; and, an epidemiological study of prenatal HIV testing rates. The presentation will qualitatively summarize and analyze the findings of these studies, and will analyze the findings through ethics theory.

Results: Informed consent has historically presented many challenges in clinical practice in general, especially in relation to the conditions necessary for autonomous decision-making to take place. Theory on autonomy suggests that conditions such as ethnic background, gender, and the power dynamic of the doctor-patient relationship all compromise autonomous decision making. A substantial amount of data suggests that greater autonomy and information will lead to lower HIV testing rates among pregnant women, giving rise to the potential for higher numbers of infected children. This presents an ethical dilemma. There are ethically valid arguments in favour of and opposed to informed consent for HIV testing in pregnancy. Policy and practice on informed consent for HIV testing in pregnancy will rely primarily on political bias and clinical practice standards.

Conclusions: Health care providers are caught in a situation of ethical uncertainty that may have an impact on their practice surrounding prenatal HIV testing.

Contact Information: Dale Guenter, Tel: 905-523-6611, Email: guentd@mcmaster.ca

STUDENT INTERNSHIPS IN CAMBODIA (III): A MULTI-SECTORAL, COMPARATIVE STUDY OF HIV/AIDS AND ALCOHOL IN CAMBODIA AND CANADA

Jillian Schuster [1]; **Ian Lubek** [1]; Sarath Kros [2]; Srilakshmi Ganapathi [3]; Jessica Cadesky [1]; Mee Lian Wong [3]; Trisha Pagnutti [1]; Bun Chhem Dy [4]; Wee Koon Ng Dilin Tang [3]; Tiny van Merode Roel Idema [5];
1-Psychology Department, University of Guelph, Guelph, ON; 2-Siem Reap Provincial AIDS Office, Cambodia and SiRCHESI, NGO; 3-Faculty of Medicine, National University of Singapore; 4- Siem Reap Provincial Health Department, Cambodia; 5-University of Maastricht, Netherlands;

Plain Language Summary: Student interns and thesis researchers from University of Guelph and National University of Singapore have since 2002 built local research and intervention capacity in Cambodia, first with HIV/AIDS prevention programs and most recently studying the interaction of alcohol and AIDS risks in the workplace, especially for beer promotion women and their restaurant customers. These women are 20% sero-positive but left out of company ARVT plans. Drinking with clients reduces condom use and may have long-term consequences associated with alcoholism. Students interning in Cambodia gather data, have helped with HIV/AIDS and alcohol risk-reduction workshops, and help pressure international beer companies to provide safe, healthy workplaces worldwide (www.fairtradebeer.com), and can engage in fundraising. A thesis study underway compares alcohol and AIDS risks in Canada and Cambodia, with a view to offering Cambodians both grass-roots health educational "best-practices" and models of effective health-promoting legislation and regulations.

Objectives: Using student internships and thesis projects to build local capacity for monitoring risk, creating and strengthening prevention and research programs dealing with the HIV/AIDS pandemic in Siem Reap, Cambodia.

Methods: Since 2002, students conduct baseline survey research, qualitative interviews, develop research skills among local medical and NGO personnel, facilitate health education workshops, and evaluate peer-educator programs for groups at risk: married women, men, young tourist vendors, and the "beer promotion women" who sell international brands in restaurants (Heineken, Budweiser, Stella, Beck, Tiger).

Results: International brewers still treat their uniformed female sales force as "advertising/ promotion costs, and refuse to pay fair wages and offer anti-retroviral therapy (ARVT). Two brewers began a "Safe Beer Selling" (SBS) program in 2004, but this has not diminished workplace drinking and risky after-work sex-for-money. Mean reported nightly beer-drinking with clients (2004-2005) remains at 1.2 litres nightly, 28 days/month. We began (with CARE, Intl.) the first Alcohol Education workshop, to be added to HIV/AIDS education outreach in 2005-6, and report initial process evaluation results.

Conclusions: Cambodian beer promoters are at major risk for HIV/AIDS and alcoholism, compared to a sample of their Canadian counterparts, serving the same brands in Ontario. International breweries are now expanding into China with exponentially larger staffs of promotion women and are not including these women in their international corporate health/safety policies or HIV/AIDS policies. Students help pressure companies to provide safe, healthy workplaces worldwide (www.fairtradebeer.com, www.ethicalbeer.com). "Beer promotion women" themselves are now active (www.beergirls.org). In future, the negative interaction of Cambodian alcohol overuse and ARVT must also be investigated.

Contact Information: Ian Lubek, Tel: 416-762-1274, Email: ilubek@uoguelph.ca