Afri-Can Forum

Special synchronicity forum of CHVI-funded Canadian and African HIV prevention and vaccine teams

January 17–19, 2013
Entebbe, Uganda

Proceedings
The Afri-Can Forum was made possible by a generous grant from Canada’s Global Health Research Initiative (GHRI), a partnership of Canadian government agencies dedicated to generating research that is relevant to health and health system decision-making in developing countries.

Forum partners

- Canada–Africa Prevention Trials (CAPT) Network
- Kenya AIDS Vaccine Initiative (KAVI)
- African Development of AIDS Prevention Trials (ADAPT2)
- Canada–Sub Saharan Africa HIV/AIDS Network (CANSSA)
- West African Platform for HIV Intervention Research (WAPHIR)
- The Benin Team
- The Free State Team
- The Nigeria Team
- The TanZamBo Project

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Message from the co-chairs

These proceedings of the Afri-Can synchronicity forum represent the work of many on-the-ground researchers in basic scientific, clinical, social and epidemiological domains, focused on capacitation of HIV prevention research in sub-Saharan Africa. Several networks supported by the Canadian Global Health Research Initiative met to present progress, to network and to plan future research. We, the co-chairs of the Forum, would like to thank the funders and the participants for sharing their work at this international meeting in Entebbe. We thank our hosts at the Uganda Virus Research Institute and the organizers, especially Rebecca Campbell, for such a successful meeting, and Open Medicine (www.openmedicine.ca) for this publication. These proceedings document the research content presented at the meeting, and future collaborations will reflect the networking success of the Forum.

Best,
Bill Cameron, Omu Anzala, Pontiano Kaleebu
Forum Co-Chairs

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PowerPoint presentations for most of the sessions and oral presentations are available as online appendices (see www.openmedicine.ca). Appendix numbers prefaced by “S” represent session presentations; those prefaced by “O” represent oral presentations.
Preface

These proceedings of the Afri-Can Forum present abstracts and other materials from this event, which took place January 17–19, 2013, at the Laico Lake Victoria Hotel in Entebbe, Uganda. The proceedings include abstracts for oral and poster presentations, summaries of the panel discussions, recommendations arising from the meeting and PowerPoint slides for most of the presentations (as online appendices). Hard copies of the proceedings may be obtained upon request to the Forum Secretariat.

The aim of the event was to provide the 13 African/Canadian research teams with an opportunity to share information about their current initiatives and to discuss ways in which they might work together to achieve greater synchronicity in those initiatives. In addition to the investigators’ presentations, the Forum included several keynote addresses, panel discussions, and other special events. The Forum had the following objectives:

- to present highlights of the Global Health Research Initiative (GHRI) teams’ capacity-building and prevention research activities
- to present overviews of the newly funded large team grants
- to provide an opportunity for the teams and networks to interact with each other and share mechanisms for making studies work
- to learn about recent advances in African regulatory and ethics review processes
- to conduct formal round table discussions on topics related to sustainability and leadership development
- to provide opportunities for informal discussions and networking among the teams
- to produce and distribute the Forum proceedings as a special supplement to Open Medicine, an independent, open-access general medical journal

This event would not have been possible without the generous support of Canada’s GHRI and the active involvement of the GHRI’s senior coordinators, Marc Cohen and Renée Larocque. The organizers would also like to thank the Alliance Coordinating Office (ACO) of the Canadian HIV Vaccine Initiative (CHVI) for its outstanding support and the Canadian Institutes of Health Research (CIHR) for providing travel support to members of the large study teams. We would also like to thank the other global networks—the International AIDS Vaccine Initiative (IAVI), the Global HIV Vaccine Enterprise, the AIDS Vaccine Advocacy Coalition (AVAC), and the Bill & Melinda Gates Foundation—for their attendance at and participation in the Forum.

The event was truly a cooperative effort of the International Program Committee, who, together with individuals from the Canada–Africa Prevention Trials Network (CAPT Network), the Uganda Virus Research Institute/International AIDS Vaccine Initiative (UVRI/IAVI), and the Kenyan AIDS Vaccine Initiative (KAVI), can take credit for making the event a great success.
Acknowledgements

The meeting was primarily supported by Canada’s Global Health Research Initiative (GHRI), in conjunction with the Canadian Institutes of Health Research (CIHR) and the Alliance Coordinating Office (ACO) of the Canadian HIV Vaccine Initiative (CHVI).

In addition, the following individuals and organizations contributed to the success of the meeting:

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International Program Committee

The Afri-Can Forum was planned and overseen by an International Program Committee, consisting of the following members:

Alash’le Abimiku
Omu Anzala
Mark Brockman
Bill Cameron
Rebecca Campbell
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Marc Cohen
Assan Jaye
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Peter Newman
Robert O’Neill
Allan Ronald
Wendy Schettler
Mark Wainberg

More information on the Committee members can be found here: www.african-forum.ca/program/program-committee
Executive summary

Introduction

From January 17 to 19, 2013, more than 130 African and Canadian researchers came together in Entebbe, Uganda, for a special African synchronicity forum. Representing the eight Global Health Research Initiative (GHRI) teams and five Canadian Institutes of Health Research (CIHR)—funded study teams, these researchers came together to share their successes and to discuss ways in which they might work more “in sync”, in order to achieve greater success in preventing the spread of HIV/AIDS.

The participants reported on a great many of their activities and discussed ways in which they might work more collaboratively in

• biomedical and clinical sciences
• behavioural research and epidemiology
• structural and operational issues

The presentations showcased the work of this African/Canadian infrastructure and reconﬁrmed the value of conducting prevention and vaccine research in the countries where it will do the most good.

The Forum

In the opening address, Pontiano Kaleebu reported on the state-of-the-art of HIV vaccine research globally, particularly research into broadly neutralizing antibody responses (i.e., blocking virus entry) and cellular responses (i.e., post-entry blocking of viral replication). Several early-phase trials are under way in these areas. However, a number of challenges must be met before the next large-scale vaccine trials can be mounted.

Noah Kiwanuka, in his address, pointed out that despite the many efforts to prevent the spread of HIV/AIDS, more than 7000 Africans still become newly infected each day, twice as many as are being started on antiretroviral therapy. Thus, the need to find more effective prevention strategies is critical. Dr. Kiwanuka stressed that prevention research must focus not only on the search for a vaccine but also on the search for more effective ways of addressing the social, cultural and behavioural causes of transmission.

Speakers in the basic science track presented an impressive array of ﬁndings from state-of-the-art African laboratory studies that are examining a wide variety of genetic mutations, immune responses and inter-subtype differences—all of which are helping to deﬁne priorities for future HIV vaccine research.

The behavioural scientists highlighted some of their work aimed at better understanding the habits of high-risk populations (sex workers, mobile communities, serodiscordant couples, young people, etc.) and ﬁnding culturally relevant strategies for involving those populations in studies.

In the area of operational research, the Forum heard reports on the mechanics of developing and implementing studies—not only small studies but also large ones (such as the HIV/AIDS Asia Regional Program [HAARP] Study)—from conceptualization and grant writing through to study initiation, management, analysis and publication.

There were reports on the training of clinical and laboratory professionals, on implementing best-practice programs, and on identifying and responding to the needs of health care workers. There was also a report on a program to train members of parliament in health policy-making.

The panel discussions also covered a wide range of issues, including the importance of interagency collaboration and leadership development as a lifelong process. In a discussion on the logistical difﬁculties of mounting large studies, Bob O’Neill urged the teams to think more like private businesses, which orchestrate comparative advantage in the marketplace by working collaboratively in speciﬁc areas. As an example, he urged them to consider the value of working together to harmonize the complex labyrinth of administrative forms and procedures with which sites have to contend when participating in different agencies’ studies.
Synchronicity
The importance of synchronicity was a recurring theme of the Forum. As the co-chairs pointed out in their welcome message, “synchronicity” is what happens when separate entities that have an affinity with each other somehow manage to achieve a connection. With fewer grant dollars becoming available, it was felt that working together is an important way of improving the cost-effectiveness of research investments. The interagency panel, for example, spoke about ways in which the African/Canadian teams might work more closely with the American-led vaccine research networks.

Recommendations
In a session entitled “Where do we go from here?”, the participants discussed several recommendations for going forward. Many of the recommendations would require additional funding, which would thus necessitate the involvement of the Canadian funding agencies. These recommendations include

- providing opportunities for continued communications and networking
- providing incentives for inter-team collaboration
- providing seed funding for the mentoring of young scientists
- permitting African co-investigators to receive payment for their work on Canadian research grants
- providing opportunities beyond the current round of funding, so that the teams could follow up on the results of their current activities

As a possible first step, it was suggested that a special face-to-face meeting be held to discuss some of the issues brought up at the Forum and to explore possible strategies for the future.

The future
It was evident from the presentations that the Canadian HIV Vaccine Initiative (CHVI) has engaged some of the best and brightest researchers in Africa and Canada. In a few short years, this broad-based network of study sites and laboratories has managed to make many valuable contributions to global HIV research. As well, it is uniquely placed to make equally valuable contributions to the development and conduct of large-scale vaccine trials.

One thing is certain—HIV prevention and vaccine research is a long-term process that requires long-term commitment. For this reason, the organizers respectfully request that the CHVI examine the success of its investments to date and identify pathways by which Canada can continue to build on this success in the years ahead.
Workshop for HIV researchers: The role of social science in HIV prevention and vaccine research

Janet Seeley
MRC/UVRI Uganda Research Unit on AIDS

The purpose of this workshop was to help biomedical scientists expand their understanding of the role of social science. Professor Seeley noted that some large studies utilize social scientists mainly in subordinate roles (for example, for the purpose of community mobilization). She urged biomedical scientists to see social science as a complementary and/or “stand-alone” field of research. In a complementary role, it can bring greater clarity and depth to the design of prevention/vaccine studies. In a stand-alone role, it can help to explain or make sense of complex behaviours.

The fundamentals of social science study design embrace both qualitative and quantitative approaches. During the planning stage, tools are developed in such a way as to ensure there will be meaningful data for analysis and interpretation at the study’s completion. The methods for obtaining data include observation, interviews, questionnaires, audiovisual documentation, written materials and records, drawings and maps. Professor Seeley emphasized that the qualitative methods must be carefully adapted to local circumstances in order to be meaningful, and they must be precisely defined (for example, differentiating between a commercial sex worker and a woman with multiple spouses). Often, social science uses a combination of structured and unstructured methods.

The following are some of the questions that need to be answered:

- How do we construct, define, measure and validate the methods to be used in the study?
- What model, theory or dimensions should we use?
- Are there indicators for the variables that translate well into specific settings?
- Will our methods actually measure what we intend them to measure? (For example; if we prescribe a drug to patients, will we need to find out whether the patients are using other drugs as well? If so, how will we find that out?)

Using the MRC/UVRI Uganda’s Good Health for Women Project as an example, Professor Seeley mentioned some points to keep in mind when designing the social science aspects of a study:

- Start with open-ended questions on potential study tools (questionnaires, checklists, etc).
- Draw a thematic framework for analyzing qualitative data.
- Be sure that different interviewers use the same script when capturing data for analysis.
- Be sure that the interviewers are comfortable with the local language.

The second part of the workshop focused on the informed consent process. Professor Seeley spoke about the values, beliefs, power dynamics and other factors that affect a person’s decision whether to participate in a study. She emphasized the importance of enhancing the participant’s experience in taking part in the study, including having a clear understanding of the objectives, as well as the risks and benefits of participation. She discussed consent as an ongoing process rather than just a one-time event, and she suggested that during the implementation of a study the investigators provide the ethics board and community advisory board with periodic progress reports, including any interim findings.

The final part of the workshop was a “hands on” session in which participants were given a sample study and asked to discuss how they might incorporate a social science perspective into it.

See online Appendix S-1 for PowerPoint presentation.
New developments in the search for an HIV vaccine

Pontiano Kaleebu
Uganda Virus Research Institute (UVRI), Entebbe, Uganda

Professor Kaleebu presented an overview of recent developments in the search for an effective HIV vaccine. He gave an update on current vaccine trials, as well as some promising candidate vaccines and some of the challenges that have to be met.

He mentioned that several follow-up studies to the RV144 (Thailand) Study are being performed to determine whether the immune responses observed in that study are causally related to protection from immunity. An effective vaccine, he explained, will likely need to induce two types of immune responses: a broadly neutralizing antibody response (i.e., blocking virus entry) and a cellular response (i.e., blocking viral replication post entry). Professor Kaleebu then outlined the process by which broadly neutralizing antibodies are utilized in vaccine development, and he explained how HIV variability presents major challenges to the discovery of an effective vaccine.

He presented a window of hope with new clinical trials using HIV adeno-associated virus type 1 (AAV-1) vector to express the PG9 antibody in HIV-seronegative patients and with an upcoming study of passive immunotherapy (VRC01) in infants.

Professor Kaleebu concluded that a great deal of progress is being made in these and other areas. He noted that the next round of efficacy trials will be complicated and expensive and will require large numbers of participants.

See online Appendix S-2 for presentation.

Combining social, behavioural and biomedical science in HIV prevention

Noah Kiwanuka
Makerere University School of Public Health, Kampala, Uganda

Dr. Kiwanuka spoke about the effectiveness of various interventions at curbing the number of new infections.

Since none of these interventions can singly eliminate HIV, it is plausible that when used in combination with each other, they can dramatically reduce or possibly eliminate new HIV infections. Prevention strategies must take into account not only the search for a vaccine but also the search for ways to address the social, cultural and behavioural factors that affect transmission (Figure S-1). Dr. Kiwanuka emphasized the necessity of collaboration among the main scientific disciplines to make a comprehensive impact on HIV transmission rates:

Professor Sewankambo highlighted ISHReCA’s objectives: research, as well as translating research products into policy and practice. He pointed out that challenges faced by ISHReCA include the establishment of a fully functional independent secretariat, the development and sustainability of the organization, and the mobilization of internal and external resources.

Professor Sewankambo informed Forum participants that discussions are continuing on how best to ensure that ISHReCA’s activities will be adopted and included in budgets of its member countries.

See online Appendix S-4 for presentation.

**Canada’s Global Health Research Initiative (GHRI): current highlights and future directions**

Marc Cohen (chair), Andrew Kambugu, Omu Anzala, Mark Brockman, Vlad Novitsky, Anne Cockcroft, Assan Jaye, Michel Alary, Alash’le Abimiku (presenters)

Mr. Cohen pointed out that the Global Health Research Initiative (GHRI) has funded nine HIV/AIDS Prevention Trials Capacity Building teams, which operate in 13 African countries (see online Appendix S-5). The program is part of the Canadian HIV Vaccine Initiative (CHVI), a coordinated effort to accelerate the development of an effective and accessible HIV vaccine.

The GHRI program has the following objectives:

- To strengthen the capacity and leadership skills of African researchers and institutions to undertake prevention trials with special focus on innovations in HIV/AIDS prevention, particularly HIV vaccines.
- To support collaboration and networking by African researchers and research users in research and policy development related to HIV/AIDS prevention trials.
- To advance the collaboration and networking of Canadian and African researchers and institutions in global HIV/AIDS prevention trial efforts.

The teams are building capacity in different ways, including building good clinical practice and improving laboratory techniques, regulatory processes and advocacy. Short- and long-term training is another major focus, as well as the development of population cohorts and the conduct of small, locally driven research projects.

Highlights from the work of the GHRI capacity-building teams:

- The Canada–Africa Prevention Trials (CAPT) Network team has been heavily focused on the creation of multisite discordant-couples cohorts, as well as on developing its Immunopaedia educational website.
(www.immunopaedia.org.za) and supporting the “WhizzKids United Health Academy,” which uses football as a context for conducting behavioural research with young people. See online Appendix S-6.

- The Kenya AIDS Vaccine Initiative (KAVI) team is building on the University of Nairobi’s strength in laboratory capacity and is also helping to promote vaccine literacy among Kenya’s populations and policy-makers. See online Appendix S-7.

- The Canada–Sub Saharan Africa HIV/AIDS Network (CANSSA) team funds small biomedical and social science projects as a way of helping its sites to strengthen their clinical and laboratory capacity. See online Appendix S-8.

- The TanZamBo team is doing similar work in Tanzania, Zambia and Botswana. See online Appendix S-9, online Appendix S-10 and online Appendix S-11.

- The African Development of AIDS Prevention Trials (ADAPT) team has been focusing on providing “in-depth” training in randomized controlled trial methodology and on training government officials to better understand and make use of research findings. See online Appendix S-12.

- In West Africa, the West African Platform for HIV Intervention Research (WAPHIR) team is filling a specific gap by strengthening immunology and virology laboratory techniques in Senegal. See online Appendix S-13.

- In Benin, a highlight of that team’s work has been the creation of a local research ethics committee.

- In Nigeria, the team is helping to establish an internationally certified vaccine research site. This will be an important resource, since this most populous of African countries has never previously been able to participate in an HIV vaccine study. See online Appendix S-14.

The individual teams’ presentations demonstrated the broad spectrum of activities under way. They also illustrated the importance of African leadership and a focus on local needs. It was also obvious that they have many similar areas of activity (for example, reproductive health, discordant-couples cohorts and laboratory training). The teams also pointed out some of the challenges they are facing; for example, administrative delays (particularly delays in completing financial and legal agreements) and complications related to conducting multisite projects (as opposed to single-site projects).

A major dividend of becoming “research ready” has been an increase in the sites’ ability to collaborate with other research networks. This is also increasing the possibility that they will be able to make a contribution to future large vaccine trials.

### Strategies for ensuring success in prevention research—field experiences from the Nairobi, Kenya, sex workers project

No summary is available for this keynote presentation by Joshua Kimani. See online Appendix S-15 for the PowerPoint presentation for this keynote address.
Building leadership skills—a lifelong pursuit

Allan Ronald, University of Manitoba (chair); Josephine Birungi, Director of Canada–Africa Prevention Trials (CAPT) Network’s The AIDS Support Organization (TASO) Jinja site; Marianne Wanjeri Mureithi, Immunologist with Kenya AIDS Vaccine Initiative (KAVI); Thumbi Ndung’u, co–Principal Investigator of the Canada–Sub Saharan Africa HIV/AIDS Network (CANSSA) Team; Alfred Amamdua Ngwa, West African Platform for HIV Intervention Research (WAPHIR) (panelists)

Dr. Ronald outlined the main characteristics of effective leaders and discussed how they can be applied in the field of health research. Leadership coaching should concentrate more on developing and sustaining strengths than on pointing out weaknesses, he noted. However, if a person has a fatal flaw in his/her character (e.g., uncontrollable anger, addictions, failure to complete tasks), such a flaw could hinder or destroy his/her ability to be an effective leader. It is critical that the leader identify and address it, even if he/she requires professional help in doing so.

Leadership skills can be innate but they can also be acquired through a conscious process of development. Dr. Ronald differentiated between “power leadership,” which is based on coercion and utility, and “principled leadership,” which is based on shared values, integrity and respect. He concluded his remarks by saying that people should develop their potential to become exceptional leaders and utilize their leadership abilities for a career that fulfills their dreams and makes a difference in society. See online Appendix S-16 for presentation.

Josephine Birungi spoke about leadership as an inner desire for personal growth. She recounted her leadership journey through various placements at Uganda’s The AIDS Support Organization (TASO) and the research opportunities that became available to her there. At a personal level, she noted, inner drive and motivation are vital. Developing leadership involves taking leadership courses, attending public lectures and working on one’s communication skills. However, it is a lot easier when there are external drivers. At the organizational level, the most important factor is to have mentors who are outstanding leaders and whose example one is able to emulate. She spoke about one mentor who gave her helpful books to read and linked her with valuable career opportunities. “As leaders, we also have an important responsibility to groom our successors,” she said. “If we do that, then we will ensure that there continues to be effective leadership after we’re gone.”

Marianne Wanjeri Mureithi echoed Dr. Birungi’s comments and described the benefits she gained from her mentors at the Kenya AIDS Vaccine Initiative (KAVI). She added that one is able to utilize his/her acquired leadership skills to benefit students, family members and others in the community.

Thumbi Ndung’u narrated his initial assumption about leaders being people who sit in big offices and do nothing. However, after becoming a leader, he realized that hard work is an essential characteristic of good leadership. He noted that people are usually not good at understanding their own strengths and weaknesses, and he encouraged leaders to network with their students and employees to obtain feedback on their own leadership performance.

Alfred Amamdua Ngwa narrated the mentoring experience he obtained from his father, who had been the head of a biology program. He also emphasized learning from one’s own mistakes as an important factor in becoming a good leader.

Making large studies work: general discussion of study management issues and possible solutions

Robert O’Neill, Canada–Africa Prevention Trials (CAPT) Network (chair)

Mr. O’Neill highlighted some of the challenges to the management of studies (and their solutions) and outlined the elements of a well-managed study. He noted that a large study involves a huge investment of time, money and people. Its budget is usually fixed and limited. If the study is to be successful, it must be managed in a structured way—with professional, efficient and business-like management mechanisms.
The skills required to successfully manage a large study are different from those required to obtain the grant. The study’s management methodology is as important as its scientific methodology, not just a subsidiary consideration. It is the framework upon which the study will either run or stall. We’ve all seen studies stall, and we’ve even seen a few studies fail. In many of those cases, the problems have been management-related rather than science-related (e.g., contract hold-ups, administrative delays, regulatory barriers, ethics concerns, participant recruitment problems). See online Appendix S-17 for presentation.

Mr. O’Neill then invited the participants to discuss some of the challenges and to suggest solutions. The following are some of the key points from that discussion.

### Challenges and solutions

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<tr>
<th>Challenges and issues</th>
<th>Recommended solutions</th>
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<tr>
<td>In certain circumstances, it would help if there were some study management standards (e.g., laboratory standards).</td>
<td>That studies utilize laboratory accreditation programs available from agencies such as the Public Health Agency of Canada (<a href="http://www.phac-aspc.gc.ca/aids-sida/about/nationallab-eng.php">www.phac-aspc.gc.ca/aids-sida/about/nationallab-eng.php</a>) and the African Society for Laboratory Medicine (<a href="http://www.aslm.org">www.aslm.org</a>).</td>
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<tr>
<td>Some large studies are not implemented in an efficient, business-like way. Face-to-face study meetings are seen as important. However, the work of studies often does not leave enough time for meetings.</td>
<td>That managers play a stronger role in reminding their team members of their responsibilities and timelines. That in-service training include clear delineation of roles and responsibilities (including the roles of the principal investigators and co-investigators). That enough time be set aside for ongoing communications and face-to-face meetings.</td>
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<td>It is often difficult to find the required expertise at the time that a study is starting.</td>
<td>That site directors begin to recruit qualified staff early in the process (well before the study contracts are signed and the funds are transferred). That the junior investigators be included from the beginning of the planning stage.</td>
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<td>Unlike Canadian investigators, many Africans depend on research projects for their salaries. Therefore, it is important that they be reimbursed for their work on studies.</td>
<td>That Canadian funding agencies permit the payment of African co-investigators for their work on research projects.</td>
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<td>There is a problem with “institutional memory,” i.e., maintaining trained research personnel beyond the end of a study. (This is due partly to the lack of available positions and partly to the fact that the locally funded programs pay much less than the externally funded research projects.) Also, there needs to be salary for the lengthy preparatory time that is spent by staff before the study starts.</td>
<td>That the Canadian government continue to make available capacity-building grants, enabling sites to maintain trained staff between studies. Also, that research teams work cooperatively with local sites to find solutions to the salary disparities.</td>
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<td>Having different management procedures, forms and templates for each study greatly compounds the workload for site staff. Study timelines are often unrealistic (e.g., projecting overly optimistic rates of recruitment). Also, there are often long delays in finalizing the contracts and transferring the funds to the site.</td>
<td>That teams get together and find a way to harmonize their studies’ management procedures, forms and templates (including contract procedures and templates).</td>
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<td>Different studies sometimes compete for staff within the same sites.</td>
<td>That teams who are conducting different studies at the same sites find a way to work in harmony to avoid competing for the same staff.</td>
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<td>Clinical trials should be more relevant to the needs of local care programs.</td>
<td>That the research agenda be “Africa-driven” or at least that the local investigators be involved in the conceptualization and planning of new studies. Also, that efforts be made to align study goals with the goals and mission of the local institutions.</td>
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Ways of working together: inter-agency panel discussion

Dianne Gagnon, Global Health Research Initiative (GHRI) (chair); Patricia Fast, International AIDS Vaccine Initiative (IAVI); Siobhan Malone, Bill & Melinda Gates Foundation; Stacey Hannah, AVAC Global Advocacy for HIV Prevention; Bill Snow, Global HIV Vaccine Enterprise (panelists)

Dr. Fast presented an overview of the work of the International AIDS Vaccine Initiative (IAVI) in creating clinical research centres and conducting HIV vaccine trials. She discussed the challenges of capacity building where there are mobile populations (access to care, participant tracking, adherence, etc.) and emphasized the need to standardize and mobilize clinical and laboratory practices.

Dr. Fast also presented some of the key synergies between IAVI and the Global Health Research Initiative (GHRI) capacity-building teams, most notably in the strengthening of laboratory capabilities. See online Appendix S-18 for presentation.

Ms. Malone discussed the Bill & Melinda Gates Foundation’s ongoing efforts to advance the studies of promising HIV pox-protein vaccine candidates (including production of pre-clinical lots and development of pre-study collaborations with host countries in southern Africa). She also announced a new Cape Town HIV Vaccine Laboratory project, which aims to build a stronger African laboratory infrastructure for large-scale studies. See online Appendix S-19 for presentation.

Ms. Hannah presented an overview of AVAC and used its work with the Ugandan Coalition for Prevention Research as an illustration of how the Coalition identifies and addresses trial design issues, develops information for lay audiences, articulates roles within the comprehensive response and facilitates collaboration between civil society stakeholders and researchers. See online Appendix S-20 for presentation.

Mr. Snow discussed the role of the Global HIV Vaccine Enterprise in the areas of coordination, collaboration and knowledge sharing. The Enterprise helps researchers, funders and other stakeholders to share their knowledge and identify areas where collective efforts and additional resources are needed. The annual AIDS Vaccine Conference is seen as the main forum for these activities. See online Appendix S-21 for presentation.

The session did not generate specific recommendations. However, the following are some opportunities mentioned by individual panelists:

- The GHRI teams should continue to work closely with international networks (e.g., IAVI) to further strengthen the local sites’ capacity to conduct research on key populations (especially young people, men who have sex with men [MSM], serodiscordant couples and mobile populations).
- Canadian government agencies should continue to involve African governments, regulatory agencies and national HIV bodies in their planning and programming, and should expand that involvement.
- The GHRI teams and the large study teams should work with the proposed new Cape Town HIV Vaccine Laboratory (which aims to build a stronger African infrastructure for large-scale studies and to facilitate career development of African laboratory scientists).

Overview of large study team projects

Novel mechanisms and strategies of protection—Julius Oyugi

We currently have no effective vaccine for the prevention of HIV, nor do we have a therapy that can completely cure HIV. The current team grant will combine the expertise of a team of cutting-edge immunologists, translational biologists and biochemists at the University of Toronto with clinical epidemiologists at the University of Nairobi (Kenya) to uncover new avenues of research that may lead to an HIV vaccine. In addition, new ideas will be explored that can be used to treat HIV infection with the use of immunotherapies. It is hoped that cross-fertilization of expertise between Kenya and Canada will lead to new discoveries that can be applied to rapidly produce an HIV vaccine. See online Appendix S-22 for presentation.

Social and behavioural research on HIV vaccines—Clinton Rautenbach

The Canadian HIV Vaccine Initiative (CHVI) Team in Social and Behavioral Research on HIV Vaccines will launch an expert interdisciplinary social science team in Canada, India and South Africa that will apply rigorous and innovative social sciences research to accelerate the development and dissemination of safe, effective and accessible HIV vaccines. The team research program addresses key challenges in ensuring fully informed consent among HIV vaccine trial participants and in engaging the preferences and concerns of vulnerable community end users throughout HIV vaccine development in order to bridge the science-to-practice gap. Each year of delay in the development and uptake of HIV vaccines results in up to 2 million new HIV infections, 2,500 in Canada alone, which might otherwise have been averted. The CHVI Team will make a significant contribution to training the next generation of HIV vaccine social and behavioural researchers in Canada and in South-South partnerships and traineeships in India and South Africa, the two countries with the highest numbers of persons living with HIV in the world. See online Appendix S-23 for presentation.
Immune responses in HIV-1 exposed uninfected infants—Ken Rosenthal

The transmission of HIV from an infected mother to her infant via breastfeeding is remarkably inefficient. Despite repeated exposure to HIV in the breast milk, the majority of infants who are exclusively breastfed (EBF) do not become infected. Interestingly, infants that are EBF are less likely to be infected by their HIV-positive mothers than infants who receive other sources of liquid or food in addition to breast milk, despite consuming more HIV-infected milk. To better understand this unusual finding, our research aims to identify factors in breast milk that protect infants from HIV infection and/or inflammatory responses of the infant gut following different feeding practices that may increase susceptibility to HIV infection. Our program of work also proposes to examine the effect of previous immune activation in the infant on immune responses to standard childhood vaccinations and to evaluate maternal attitudes and beliefs about breastfeeding and mothers’ willingness to enroll their infants in future HIV vaccine trials. We have assembled a strong, international multidisciplinary team of investigators to carry out these studies in Nigeria and South Africa, the countries with the highest number of HIV-positive pregnant women. Understanding modes of natural protection as well as immune activation in the HIV-exposed but uninfected infant provides information critical to HIV vaccine development, especially to testing in developing countries with high HIV prevalence. See online Appendix S-24 for presentation.

Developing a multidisciplinary strategy to examine HIV risk and clinical outcomes in South African adolescents—Mark Brockman

Despite ongoing prevention efforts, HIV incidence in South African youth remains remarkably high. Inclusion of high-risk adolescent populations in vaccine trials will be essential to ensure the success of future efforts, but limited data exist on social, ethical, political and regulatory barriers to recruit minors into large-scale trials in South Africa. Biological changes, particularly at mucosal sites, occurring in adolescents may alter their risk of infection and/or complicate immunologic end points of vaccine studies, but there are limited data available to address these issues in any population. We have assembled a multidisciplinary team of social scientists, ethicists, clinicians and biomedical researchers to examine these questions using existing cohorts of adolescents recruited in Soweto and Durban, South Africa. Results are anticipated to inform social and biomedical aims of future HIV vaccine studies involving minors. See online Appendix S-25 for presentation.

The Botswana–Canada AIDS vaccine discovery partnership—Mark Wainberg

The aim of our research is the discovery and characterization of highly potent, broadly neutralizing antibodies that target HIV. We will use innovative immunologic techniques and cutting-edge technologies to search for these rare antibodies in persons infected with HIV. It is hoped that such antibodies will allow a better understanding of the host’s ability to mount an immune response that is capable of halting HIV transmission. Such antibodies will provide stepping stones toward the design of novel HIV vaccines and allow the development of an effective HIV vaccine for the global community. We have partnered with colleagues in Botswana to pursue this challenging endeavour in HIV vaccine discovery. See online Appendix S-26 for presentation.

Coordinating the CHVI Alliance and building linkages—an update from the Alliance Coordinating Office

Wendy Schettler, Tanya Merke Epp

Alliance Coordinating Office (ACO) of the Canadian HIV Vaccine Initiative (CHVI)

The Research and Development Alliance of the Canadian HIV Vaccine Initiative (CHVI) is a multisector partnership funded by the Canadian government for the purpose of assisting in the discovery and development of an effective HIV vaccine. To coordinate that effort, the Alliance Coordinating Office (ACO) helps to integrate basic, clinical and social sciences, enhances capacity-building efforts, supports the development of new researchers and strengthens linkages among the various stakeholders.

The presentation focused primarily on the establishment of a virtual community for HIV vaccine researchers. Ms. Schettler described it as a place where people with an interest in HIV vaccine research can come together online to share research, exchange ideas, seek information and participate in collaborative projects. Ms. Merke Epp explained that all Forum participants were invited to join the virtual community, and she reviewed the registration process. The ACO also provides regular e-bulletins to help members stay informed about relevant news and developments in the field of HIV vaccine research. See online Appendix S-27 for presentation.
Biomedical and clinical sciences

O-1 HIV resistance to dolutegravir is conferred by mutations at integrase positions R263K and H51Y that simultaneously diminish viral replication fitness

Thibault Mesplede, Peter Quashie, Mark A. Wainberg
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Purpose: We selected for resistance in tissue culture against dolutegravir (DTG), a second-generation HIV integrase strand-transfer inhibitor that has been studied in phase 3 clinical trials, in order to try to characterize the resistance profile of this compound.

Methods: HIV-1 of different subtypes was grown in both MT-2 cells and peripheral blood mononuclear cells over protracted periods, with the concentration of DTG being incrementally increased from an initial concentration of 0.05 nM (i.e., 4 times less than the half-maximal effective concentration). After a total of 6 months of growth, a final drug concentration of 50–100 nM was achieved, beyond which virus could no longer be grown. Viral DNA was then sequenced to reveal the presence of mutations that might be responsible for resistance to DTG, and the biological relevance of these mutations was confirmed through site-directed mutagenesis experiments in which individual mutations or combinations of mutations were studied in comparison with wild-type (wt) virus in tissue culture and with recombinant HIV integrase enzyme in biochemical assays.

Summary: The most common integrase resistance mutation to arise in subtype B and recombinant A/G viruses was R263K followed by H51Y. In the case of subtype C viruses, the most common mutation was G18R followed by H51Y. The presence of R263K alone conferred an approximate 2- to 4-fold level of resistance to DTG in culture and a 30% drop in levels of

Fig. O-1: Strand-transfer activities of purified recombinant integrase proteins. (A) Recombinant integrase proteins INWT, INH51Y, INR263K and INH51Y/R263K were purified (lanes 1 to 5) and used to measure strand-transfer activity in relative fluorescent units per hour (RFU/h) in the presence of 18 nM target DNA and various concentrations of purified recombinant protein. (B) Strand-transfer activity (in RFU/h) was measured in the presence of 450 nM purified recombinant protein and the indicated concentration of target DNA. Lines are fits; error bars indicate ± standard error of the mean.
Conclusions: R263K and H57Y can combine to augment levels of resistance to DTG but result in a more severe attenuation of viral replication capacity and integrase strand-transfer activity than R263K alone. These data suggest that viruses containing both mutations may be at a severe replicative disadvantage and help to explain why primary resistance to DTG has arisen so rarely in the clinical studies performed to date. These findings are also consistent with recent clinical results that described the R263K mutation in several patients who were treated with DTG after failing therapy with other drug classes but who had never previously received an integrase strand-transfer inhibitor.

See online Appendix O-1 for the PowerPoint presentation.

O-2 Inter-subtype differences in the effect of a rare p24 Gag mutation on HIV-1 replicative fitness

Denis Chopaera, Mark Brockman, Carolyn Williamson, Zabrina Brumme

Simon Fraser University, Burnaby, British Columbia, Canada

Background: Certain immune-driven mutations in HIV-1, such as those arising in p24Gag, decrease viral replicative capacity. However, inter-subtype differences in the replicative consequences of such mutations have not been explored. This study explored the impact of a rare Gag mutation, M250I, on subtype B and C viral fitness.

Materials and methods: This study drew upon host/viral genetic and replicative fitness data from subtype B (803 chronic untreated and 69 elite controllers) and subtype C (405 chronic untreated and 53 seroconverters) cohorts. Phylogenetically informed methods were used to detect human leukocyte antigen (HLA) alleles and Gag amino acids associated with codon 250. In vitro viral replication was carried out using a chimeric recombinant system in an NL4-3 backbone or in peripheral blood mononuclear cells using a subtype C backbone. The PEP-FOLD program was used for protein modeling.

Results: In subtype B, the p24Gag M250I mutation is extremely rare in chronically infected individuals (0.6%) but enriched among elite controllers (7.2%) (p = 0.0005). Among both groups, it is enriched among persons expressing HLA-B*58 supertype alleles (p < 0.01). By contrast, in subtype C, it is a relatively common minor polymorphic variant (10%–15%) whose appearance is not associated with a particular HLA. When introduced via site-directed mutagenesis, M250I reduces in vitro viral replicative capacity in both subtype B and subtype C sequences. However, whereas in subtype C, downstream compensatory mutations at p24Gag codons 252 and 260 reduce the adverse effects of M250I,
fitness costs in subtype B appeared difficult to restore. Indeed, participant-derived subtype B sequences harboring M230I exhibited in vitro replicative defects while those from subtype C infected participants did not. Also, whereas individuals chronically infected with subtype B viruses carrying M230I tended to experience modestly lower viral loads, this was not the case in subtype C. The structural implications of M230I were predicted by protein modeling to be greater in subtype B than in subtype C, providing a potential explanation for its lower frequency and enhanced replicative defects in subtype B.

**Conclusion:** In addition to accounting for genetic differences between HIV-1 subtypes, the design of cytotoxic T-lymphocyte-based vaccines may need to account for differential effects of host-driven viral evolution on viral fitness.

See online Appendix O-2 for PowerPoint presentation.

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**O-3 Immune quiescence phenotype observed in the genital tract of highly exposed seronegative female commercial sex workers**


University of Manitoba, Winnipeg, Manitoba, Canada

**Background:** Understanding the early events during heterosexual HIV transmission at the genital mucosa is necessary to develop a safe and efficacious HIV microbicide or vaccine. A recent workshop highlighted the benefits of studying highly exposed seronegative (HESN) individuals in order to identify and describe correlates of HIV protection. In an HESN cohort of commercial sex workers in Nairobi, Kenya, we have described a state of reduced systemic T cell immune activation termed immune quiescence. However, the extent of immune quiescence at the genital mucosa is not known. This study characterized the female genital mucosal profile of cells, cytokines and chemokines involved in immune activation and lymphocyte recruitment among HESN individuals.

**Methods:** Cervicovaginal lavage and plasma from commercial sex workers from the Majengo clinic in Nairobi, Kenya (57 HIV-negative individuals followed for <3 years; 68 HIV-infected and 55 HESN individuals followed for >7 years), were analysed for the presence of 22 cytokines/chemokines and five antiproteases previously associated with resistance to HIV infection. Activation of cervicovaginal cells was analysed by multiparametric flow cytometry.

**Results:** HESN women have a unique pattern of mucosal chemokine/chemokine expression. HESN subjects showed lower expression of MIG, IP-10 and IL-10 as well as higher levels of antiproteases. Among the HESN women there was a distinct chemokine gradient between the blood and genital mucosa relative to control women.

**Discussion:** MIG and IP-10 are important regulators of T cell trafficking to the genital mucosa, while IL-10 is an indicator of immune activation. The reduced levels of these cytokines/chemokines together with the unique correlations observed with antiprotease expression among HESN women suggest that the immune quiescent phenotype extends to the female genital tract. Reducing the number of activated CD4+ T cells in the female genital tract could limit cellular targets for HIV infection and may be an important component to resisting HIV infection.

See online Appendix O-3 for PowerPoint presentation.

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**O-4 Longitudinal analysis of immune quiescence and impact of commercial sex work in HIV-exposed seronegative (HESN) sex workers from Nairobi, Kenya**

Genevieve Boily-Larouche, Sheryl Kirwan, Julie Lajoie, Joshua Kimani, Keith R. Fowke

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**Introduction:** HIV is a major public health issue, infecting more than 34.2 million individuals worldwide and affecting many more. In African countries, like in Canada, heterosexual transmission is now the main route of infection and women from sub-Saharan Africa remain disproportionately affected by the HIV epidemic, accounting for 58% of people living with HIV. A priority for HIV research is to understand the nature, quality and quantity of protective immune responses at the mucosal barrier, the site of entry of HIV infection, in order to develop effective prevention strategies. The Pumwani Sex Worker Cohort of Nairobi, Kenya, contains a small subgroup of women who are intensively exposed to HIV-1 yet remain uninfected. Understanding immunological factors that contribute to preventing HIV-1 infection in these women will provide insights on how to design effective HIV prevention tools. Previous studies have demonstrated that HIV-exposed seronegative (HESN) commercial sex workers have an immunologically quiescent phenotype. The immune quiescent phenotype is defined as having at the genital tract lower resting levels of key immune modulators, such as cytokines/chemokines, lower systemic levels of activated T cells (the HIV target cells) and higher levels of regulatory T cells (Tregs), which function to limit immune activation. Despite this quiescent phenotype, HESNs show no sign of immune
impairment as they have a normal ability to mount an immune response. Multiple factors may drive immune quiescence in HESN sex workers and contribute to reducing their susceptibility to HIV infection. Sex work results in exposure to very strong immune stimulants and affects the level of immune activation. It has been observed that reduction of sexual partners or interruption in sexual activities results in late seroconversion in previously resistant women resuming commercial sex work. Thus, protection is not absolute and may wane during interruption of commercial sexual activities. In HESN sex workers, adoption of an immune quiescent phenotype in response to the strong sex-driven immune stimulants may limit target availability and prevent the establishment of a productive HIV infection.

**Methods:** In a pilot experiment, levels of activation markers on cervical and peripheral lymphocytes were measured by flow cytometry in samples collected from women interrupting sex work for 4–8 weeks to return to their home village. HESN, newly enrolled negative and HIV-positive sex workers from the Pumwani Sex Worker Cohort were enrolled and samples were collected before, following an interruption in work and 6–9 months after resumption of commercial sexual activities.

**Results and discussion:** Preliminary data have demonstrated that a break from sexual activities results in a reduction of systemic and mucosal immune activation markers during the work interruption period in HIV-positive women that is followed by a re-increase in these activation markers upon resumption of sexual activities (Fig. O-4-1). In the vaginal mucosa of HESN women, levels of cervical immune activation remain constant, while they increase after resuming sex work in new negative controls to reach higher levels than in HESN women (Fig. O-4-2). Activated CD4+ T cells are the main targets for HIV infection and their recruitment at the female genital tract following resumption of sex work is likely to influence susceptibility to HIV infection. The ability of HESN sex workers to downregulate and maintain low levels of sex-work-driven immune activation, and therefore low levels of HIV targets at the infection site following a sex work interruption period, may contribute to their protection against HIV acquisition.

**Conclusion:** A better capacity to maintain low levels of immune activation in the vaginal tract following work interruption may contribute to protecting HESN sex workers from acquiring HIV infection. To design effective prevention tools, we need to understand how the HESN women's exceptional regulation of the levels of immune activation is achieved. The sex interruption model is a way to remove and then reintroduce a powerful immune stimulant and measure the regulation of immune activation. This study provides the first insights into the impact of sex work interruption on the regulation of immune activation at the female genital tract. Understanding the natural protective mechanisms that regulate the number of HIV targets at the infection site will provide insights on strategic interventions that...
reduce targets at the female genital tract and hence prevent HIV transmission.

See online Appendix O-4 for PowerPoint presentation.

O-5 Assessing the impact of sexual activity on systemic immune activation among HIV-exposed seronegative female sex workers at Pumwani Clinic, Nairobi

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Kenya AIDS Vaccine Initiative (KAVI), University of Nairobi, Nairobi, Kenya

Sex work continues to be a source of livelihood with social networks in breadth and depth for risks of HIV acquisition and transmission. More women than their males are contracting new HIV infections through the heterosexual route in sub-Saharan Africa. A subset of HIV-exposed seronegative (HESN) female sex workers remain uninfected for >7 years of follow-up and exhibit the immune quiescent phenotype with few activated T cells. We hypothesize that immune quiescence is associated with protection against HIV by limiting the number of HIV target cells. It may also provide opportunities for developing new treatments including microbicides and/or vaccine candidates for HIV.

See online Appendix O-5 for PowerPoint presentation.

O-6 Is bacterial vaginosis just the tip of the iceberg as to the risk of HIV related to vaginal flora abnormalities?

Fernand Aimé Guédou, Lut Van Damme, Jennifer Deese, Michel Alary
Université Laval, Centre de recherche FRSQ, Centre hospitalier affilié universitaire de Québec, Québec, Canada

Background: There has been accumulating evidence suggesting that bacterial vaginosis (BV) is an important risk factor for...
Objective: The authors analysed data from female sex workers screened prior to participation in a microbicide trial to examine the association between prevalent vaginal flora abnormalities and HIV infection, with special emphasis on the role of the intermediate vaginal flora (IVF) in this association.

Methods: Data from the KAMPALA, COTONOU, CHENNAI and Mudhol/Jamkhandi sites were analysed. Participants were interviewed and provided blood for HIV and syphilis antibody testing, genital samples for the diagnosis of vaginal flora abnormalities (using Nugent score) and other reproductive tract infections. Log-binomial regression was used to estimate the HIV prevalence ratio (PR) in relation to IVF and bacterial vaginosis (BV).

Results: Among 1367 women, BV, IVF and HIV prevalences were 47.6% (95% CI = 45.0% to 50.3%), 19.2% (95% CI = 17.1% to 21.2%) and 27.0% (95% CI = 24.6% to 29.3%), respectively. In multivariate analysis, adjusting for study site, age, years of education, occupation, female sterilisation, oral sex, past history of sexually transmitted infection, gonorrhoea and candidiasis, IVF was significantly associated with HIV infection with a PR similar to that of BV (adjusted PR = 1.56 (95% CI = 1.22 to 1.98) and 1.48 (95% CI = 1.20 to 1.84), respectively).

Conclusions: Though the cross-sectional design of the study precludes direction interpretation of the findings, the data do suggest that IVF may be as important as BV in HIV acquisition. The authors recommend prospective research to better understand the association between IVF and HIV acquisition. If this association is confirmed, controlling abnormal vaginal flora in female sex workers may be an untapped strategy for HIV prevention in developing countries with concentrated epidemics where sex work plays a pivotal role in the dynamic of the epidemic.

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See online Appendix O-6 for PowerPoint presentation.

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**0-7 Soluble Toll-like receptor 2 (sTLR2) is significantly elevated in HIV-1-infected breast milk and inhibits HIV-1 infection and inflammation**

Bethany M. Henrick, Xiao-Dan Yao, Kakon Nag, Anna G. Drannik, Alash’le Abimiku, Kenneth L. Rosenthal

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Background: The majority of infants who breastfeed from their HIV-positive mothers remain uninfected despite constant and repeated exposure to virus over weeks to years. This phenomenon is not fully understood but has been closely linked to innate factors in breast milk. Indeed, breast milk consists of a complex milieu of innate and adaptive immune factors, including maternal antibodies, immune cells and innate antimicrobial and immunomodulatory factors. Surprisingly, many innate factors in milk have not been well characterized or their activities elucidated. Over the last decade tremendous advances have been made in our understanding of innate immunity and its importance in protection against infection. The innate immune system relies on an early warning system of cellular receptors, called pattern recognition receptors (PRRs), which detect pathogen-associated molecules, alert our bodies to infection and activate immune responses. Toll-like receptors (TLRs) are one family of innate PRRs and there are 10 TLRs in humans. TLR2 is relatively unique since it can form heterodimers with TLR1, TLR6 or TLR10 and can detect a large breadth of pathogens. In contrast to other TLRs, TLR2 is also found as a soluble form (sTLR2) in mucosal fluids. Interestingly, sTLR2 is found at a high level in human milk and was shown to significantly inhibit inflammation triggered by pathogens. Recently, we hypothesized and were the first to demonstrate that sTLR2 in human milk inhibited immune activation/inflammation and directly inhibited HIV-1 infection.

Methods: This study was approved by the McMaster Research Ethics Board and made use of milk samples obtained from uninfected women in Canada and historic specimens from HIV-infected and uninfected women in Nigeria (provided by Dr. Alash’le Abimiku). All participants provided voluntary written informed consent. Following collection, milk was separated into lipid, supernatant and cellular fractions and stored appropriately. sTLR2 was immunodepleted from milk using anti-TLR2 Abs and Protein G Sepharose columns. A cell line that stably expressed TLR2 (TZMbl-2) was generated following transformation of TZMbl cells with TLR2. Cytokine and chemokines were measured using enzyme-linked immunosorbent assay. In vitro HIV infection was determined and compared using TZMbl and TZMbl-2 cells.
TLRs were measured using quantitative reverse-transcription polymerase chain reaction.

Results: We previously showed that sTLR2 immunodepleted breast milk, compared to mock-depleted breast milk, incubated with Pam3CSK4, led to significant increases in IL-8 production in a TLR2-dependent fashion in U937, HEK293-TLR2 and intestinal epithelial cells (Caco-2). Likewise, sTLR2 depletion of breast milk led to significant (p < 0.001) increases in HIV-1 infection in vitro. Here, extending these findings, our results demonstrate that sTLR2 produced in vitro from a stably transformed cell line significantly reduced cell-free R5 HIV-1 infection in TZM-bl reporter cells at various infectious doses, and this effect could be neutralized following treatment with anti-TLR2 antibodies. As well, sTLR2 significantly reduced pro-inflammatory IL-8 cytokine production in cells exposed to cell-free virus and this could be reversed by addition of TLR2 antibodies. Next, we determined the levels of sTLR2 in milk from HIV-infected and uninfected women. Our results showed significantly increased sTLR2 in the milk of HIV-infected Nigerian women compared to that of uninfected Nigerian women and women in Canada. The level of sTLR2 in milk correlated with p24 virus levels. Breast milk contains TLR2 activity of elaﬁn depends on its nuclear localization and altered innate immune activation in female genital epithelial cells

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Cervicovaginal lavage (CVL) fluid is a natural source of innate antimicrobial factors in the female genital tract. Elaﬁn (E) and its precursor trappin-2 (Tr) are alarm antiproteases that are found in serum and mucosal ﬂuids and possess antimicrobial, tissue repair and immunomodulatory activities. Recently, Tr and E (Tr/E) were associated with HIV-1 resistance in the CVL of highly HIV-exposed uninfected commercial sex workers (CSWs) in Nairobi. Here, we conﬁrmed that CVLs from HIV-1-resistant (HIV-R) compared to HIV-1-susceptible (HIV-S) CSWs contained signiﬁcantly higher levels of Tr and E. We assessed anti-HIV activity of CVLs and recombinant Tr and E on genital epithelial cells (ECs) that possess (TZM-bi) or lack (HEC-1A) canonical HIV-1 receptors. Our results showed that immunodepletion of 30% of Tr/E from CVLs accounted for up to 60% of total anti-HIV activity of CVLs. Knockdown of endogenous Tr/E in HEC-1A cells resulted in signiﬁcantly increased shedding of infectious R5 and X4 HIV-1. Further, pretreatment of R5, but not X4, HIV-1 with either Tr or E led to inhibition of HIV infection of TZM-bi target cells. Interestingly, when either HIV-1 or cells lacking canonical receptors were pretreated with Tr or E, HIV-1 attachment and transcytosis were signiﬁcantly reduced. Determination of the 50% inhibitory concentration (IC50) indicated E was ~130 times more potent than Tr, despite their equipotent protease inhibitory activities. Using tagged and untagged recombinant Tr/E proteins, we showed that the anti-HIV-1 activity of E depended on its unmodiﬁed N-terminus and altered cellular immune activation, but not its antiprotease activity. Speciﬁcally, exogenously added unmodiﬁed N-terminus E entered the nucleus and reduced viral attachment/entry and transcytosis, preferentially affecting R5- but not X4-HIV-1. Further, anti-HIV activity of E was associated with significantly decreased HIV-1-triggered IL-8 release, attenuated NF-kB/p65 nuclear translocation and signiﬁcantly modulated mRNA expression of innate sensors TLR3 and RIG-I in HEC-1A cells. Most importantly, we found that elevated Tr/E in CVLs of HIV-R CSWs was associated with lower expression of TLR2, TLR4 and RIG-I in the genital ECs from this cohort, suggesting a link between Tr/E, HIV resistance and modulated innate viral recognition in the female genital mucosa.

Based, in part, on Drannik AG, Nag K, Yao XD, Henrick BM, Ball TB, Plummer FA, et al. Anti-HIV-1 activity of elaﬁn depends on its nuclear localization and altered innate immune activation...

See online Appendix O-8 for PowerPoint presentation.

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**O-9 Development of a quantitative HIV-1 and HIV-2 real-time polymerase chain reaction (PCR) for HIV prevention research**

**Alfred Amambua-Ngwa, Alberta Davis, Abraham Alabi, Assan Jaye**

Medical Research Council Unit, Banjul, Gambia

**Background/aim:** The study aimed to develop a real-time quantitative polymerase chain reaction (PCR) assay modeled on an enzyme-linked oligonucleotide luminometric assay (ELONA) for detection and monitoring of HIV-1 and HIV-2 viral loads in treatment cohorts as well as therapeutic and vaccine trials.

**Method:** Quantitative real-time PCR assay was carried out using dye-labeled specific primers targeting long terminal repeats (LTR) of HIV-1/HIV-2 RNA purified from serum with the QIAamp viral RNA purification kit. Thermal cycling was performed in an ABI 7300 sequence detection system. A standard curve was generated from tissue culture supernatant of HIV-1 virus (strain U455) or HIV-2 virus (strain CBL23) grown in 8166 cells. To control for extraction efficiency and non-specific inhibition of reverse transcription and quantitative real-time PCR (qPCR), a synthetic RNA sequence, derived from the LTR of HIV-1/HIV-2 containing the PCR primer binding sequences but replacing the probe-binding sequence with a random sequence, is included as internal control. Each assay is calibrated against an international HIV RNA positive standard for inter- and intra-assay reproducibility. Uninfected samples are used as the negative control.

**Results:** The qPCR assay showed good intra- and inter-assay reproducibility over a wide dynamic range (10^0 to 1 × 10^8 copies/mL) and correlated well with those from ELONA (r = 0.91, p < 0.001). Viral load levels for both HIV-1 and HIV-2 could be determined concurrently in co-infected samples using MGB probes specific to each pathogen. Transformation of the ELONA into qPCR reduced sample processing time by 50%. The assay was easily done from 200 μL of serum and from dried blood spots.

**Conclusion:** Quantitative real-time PCR is reliable, accurate, and reproducible in determining the viral load of HIV-1 and HIV-2 infections. The fast sample processing time and ease of use of the assay permit its application to monitor the efficacy of HIV therapy and response to vaccines. We envisage optimizing an HIV-2 qPCR targeting pro-viral DNA to include a wide variety of specimens including filter paper blood spots from infant infections.

See online Appendix O-9 for PowerPoint presentation.

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**O-10 Field study of the utility of dried blood spots (DBS) for HIV-1 drug resistance (HIVDR) genotyping in Kampala, Uganda: storage for 2 weeks and shipping at ambient temperature has no effect on genotyping efficiency**

**Neil Parkin, Karidia DIALLO, Chris M. Parry, Shem Mwebaza, Richard Batamwita, Joshua DeVos, Nicholas Bosa, Fred Lyagoba, Brian Magambo, Michael Jordan, Robert Downing, Pontiano Kaleebu, Chunjio Yang, Silvia Bertagnolino**

Medical Research Council – Uganda Virus Research Institute (MRC/UVRI) Uganda Research Unit on AIDS, Entebbe, Uganda

**Background:** Dried blood spots (DBS) are an alternative specimen type for HIV drug resistance (HIVDR) genotyping in settings without resources for collection, storage and shipment of frozen plasma. Data relating to DBS storage and shipment conditions in real-world settings are limited. We compared genotyping rate and resistance profiles from DBS stored and shipped at different temperatures to those of plasma specimens collected from virologically failing patients in Uganda.

**Methods:** Plasma and 4 DBS cards from anti-coagulated blood, and a fifth card from fingerprick blood, were prepared from 103 patients receiving antiretroviral therapy (ART) for >6 months with viral loads of >1000 copies/mL. DBS were dried overnight, packaged in plastic bags containing desiccant and a humidity indicator, stored at ambient temperature (AT) for 2 or 4 weeks or frozen at −80°C, and shipped from Uganda to the United States at AT or frozen on dry ice for genotyping using a sensitive in-house method. Temperature loggers were used to monitor DBS AT shipments.

**Results:** Median plasma viral load was 4.8 log10 copies/mL (range 3.0–6.5). Median time on ART was 46 months (range 0.5 to 120). Peak temperatures during shipment were between 28°C and 40°C. Plasma (97%) and DBS (98%) stored and shipped frozen were genotyped with similar efficiency. DBS stored frozen (97%) or at AT for 2 weeks (93%) and shipped at AT had similar genotyping rates. Genotyping rate was reduced for DBS stored at AT for 4 weeks (89%, p = 0.03) or prepared from fingerprick blood (78%, p < 0.001), compared to DBS prepared from anti-
coagulated blood and handled similarly. Ninety per cent of patients had mutations associated with resistance to nucleoside reverse transcriptase inhibitors (predominantly M<sub>184V</sub>, M<sub>41L</sub> and T<sub>215Y</sub>), 88% to non-nucleoside reverse transcriptase inhibitors (mostly K<sub>103N</sub> and G<sub>90A</sub>) and 4% to protease inhibitors. HIVDR profiles were similar between plasma and DBS specimens.

**Conclusions:** Genotyping rates were unchanged when DBS were stored dry at AT for 2 weeks in an African setting compared to frozen plasma or frozen DBS. AT shipment of previously frozen DBS does not affect genotyping efficiency. DBS prepared directly from fingerprick had a lower genotyping rate. This study delineates optimal DBS collection, storage and shipping conditions and demonstrates that DBS are a suitable specimen type for genotyping in resource-limited settings.

See online Appendix O-10 for PowerPoint presentation.

**O-11 DNA methylation as an epigenetic marker in HIV-2 disease in West Africa**

Alberta Davis, Weijing He, Alfred Amambua-Ngwa, Soulemane Mboup, Sunil K. Ahuja, Assan Jaye

Medical Research Council Unit, Banjul, Gambia; Department of Medicine, University of Texas Health Science Center, San Antonio, Texas, USA; Université Cheikh Anta Diop, Dakar, Senegal

**Background:** Infection with HIV-2 mainly presents as a non-progressive disease and mortality rates are lower than those for HIV-1 infections. However, in about 20% of HIV-2 infections, high viral loads and rapid decline of CD<sub>4</sub> T cells depict a clinical presentation that is indistinguishable from AIDS seen in HIV-1 disease. Clinical progression or non-progression of HIV-2 infections to AIDS is thought to be due to variations in host factors that modulate disease progression, including the expression of genetic variants of viral entry host factors like the chemokine receptor 5 (CCR5). Therefore, understanding the role of genetic and epigenetic variations of CCR5 in HIV-2 non-progression could

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**Fig. O-11-1:** Percentage methylation across CpG sites in CCR5. Distal window CpGs −41 to −37 (A), promoter 2 CpGs −31 to −28 (B), intron 2 CpGs −6 to −1 (C) and IL-2 CpG −1 (D) in 12 progressors, where L/H represents low CD<sub>4</sub> count (<200 cells/µL) and high viral load (>10,000 copies/mL), compared to 12 non-progressors, where H/L represents high CD<sub>4</sub> count (>500 cells/µL) and undetectable viral load (<100 copies/mL). The p values were calculated with the non-parametric Mann–Whitney U test.
be important for development of new therapeutic strategies and vaccine interventions.

**Aim:** Here we investigate the role of the epigenetic mechanism DNA methylation on CCR5 and a cytokine proliferative marker of T cells, IL-2, in distinguishing clinical progression and non-progression in HIV-2 disease.

**Methods:** Thirty-six HIV-2 patient samples were collected from the bio-bank repository of the West African Platform for HIV Intervention Research, which included patients from the former Medical Research Council Clinical Cohort in Gambia. Samples were categorized on the basis of longitudinal records (follow-up duration of at least 10 years) of CD4 count and viral load measurements as progressors (individuals with low CD4: <200 cells/µL; and high viral load [VL]: >10,000 copies/mL) or non-progressors (individuals with high CD4: >500 cells/µL; and low VL: <100 copies/mL). This included 15 males and 21 females. DNA was extracted from frozen peripheral blood mononuclear cells using a QIAamp DNA mini kit and methylation levels were determined at specific CpG dinucleotides in CCR5 cis-regulatory regions (distal window [−41 to −37], promoter 2 [−31 to −28], intron 2 [−6 to −1] and IL-2 [−1]) by bisulfite DNA conversion followed by pyrosequencing (EpigenDx, Hopkinton, MA). Continuous variables were analyzed using the non-parametric Mann–Whitney U test when comparing two groups. Differences were considered significant at \( p < 0.05 \). All statistical analyses were performed using GraphPad Prism for Windows, version 5.0 (GraphPad software).

**Results:** Non-progressors had significantly higher methylation levels compared to progressors at the CCR5 distal window (\( p = 0.0072 \)) and intron 2 (\( p = 0.0164 \)) (Fig. 11-1). Methylation levels were also significantly higher in individuals with CD4 counts >500 cells/µL than in those with counts lower than 200 cells/µL at the CCR5 distal window (\( p = 0.0021 \)) (Fig. 11-2). Conversely, IL-2 methylation was higher in progressors (\( p = 0.0209 \)) and this correlated with lower CD4 counts (\( p = 0.0129 \)) (Fig. 11-1, Fig. 11-2). However, no significant difference was observed between progressors and non-progressors at CpGs in promoter 2 of CCR5. These results suggest that non-progressors may be controlling viremia through the down-regulation of CCR5 receptor expression, while maintaining HIV-2 specific responses through the production of IL-2.

Fig. 11-2: Percentage methylation across CpG sites in CCR5. Distal window CpGs −41 to −37 (A), promoter 2 CpGs −31 to −28 (B), intron 2 CpGs −6 to −1 (C) and IL-2 CpG −1 (D) in 21 individuals with high CD4 count (>500 cells/µL) versus 15 individuals with low CD4 count (<200 cells/µL). The \( p \) values were calculated with the non-parametric Mann–Whitney U test.
Conclusion: The methylation of DNA at the CCR5 receptor, indicating lesser expression of the receptor, was higher in HIV-2 non-progressors. These preliminary findings provide a basis for further investigation of methylation and genetic variations on the CCR5 locus that could be influencing disease outcomes particularly in HIV-2 infections.

See online Appendix O-11 for PowerPoint presentation.

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**Behavioural science and epidemiology**

**O-12 Factors associated with being willing to have an HIV test among adolescents living in Soweto, South Africa**

Busi Nkala, Janan Dietrich, Matamela Makongoza, Celokuhle Tshabalala, Sanele Mdanda, Angela Kaida, Robert Hogg, Glenda Gray, Cari Miller

Perinatal HIV Research Unit (PHRU), Soweto, South Africa

**Background:** Recently, the South African government implemented a mass HIV-testing campaign to support linkages to HIV-related healthcare services among citizens living in this HIV-endemic country. Adolescents (aged 14–19 years) are an important population with respect to HIV and sexual and reproductive health as this is the age when sex is often initiated and patterns of behavior and health service utilization are established. We sought to measure adolescents’ willingness to have an HIV test and associated factors.

**Methods:** Study participants were recruited through Kganya Motsha Adolescent Centre and the Perinatal HIV Research Unit’s Botsha Bophelo adolescent health project. Eligibility criteria included age 14–19 years and living in Soweto. Targeted sampling was used to ensure representation from all townships within Soweto. Demographic and clinical variables of interest were compared between adolescents who responded they were willing to have an HIV test and those who were not. Multivariable logistic regression was used to identify independent predictors of willingness to have an HIV test.

**Results:** Overall, 21% of adolescents reported being unwilling to have an HIV test (144/699) and factors associated with unwillingness were male gender (adjusted odds ratio [AOR]: 1.42; confidence interval [CI]: 0.97–2.09) and having no high school education (AOR: 1.99; CI: 1.06–3.71). Inverse associations with being unwilling to test included ever testing for HIV (AOR: 0.53; CI: 0.35–0.82) and younger age (AOR: 0.84; CI: 0.71–0.98). For female participants, ever having forced sex (AOR: 2.31; CI: 1.08–4.12) was the only factor associated with unwillingness to have an HIV test. For male participants, factors associated with being unwilling to test were having no high school education (AOR: 2.43; CI: 1.04–5.63) and ever having an HIV test (inverse association; AOR: 0.49; CI: 0.26–0.94).

**Interpretation:** Although most adolescents in Soweto are willing to have an HIV test, two in ten are reluctant. Those unwilling may be at higher risk for HIV infection due to social and structural mechanisms that influence gender norms, including disenfranchisement of young males from the education system and the experience of sexual violence by young females.

See online Appendix O-12 for PowerPoint presentation.

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**O-13 Decline in the prevalence of HIV and sexually transmitted infections among female sex workers in Benin over 15 years of targeted interventions**

Luc Béhanzin, Souleymane Diabaté, Djimon Marcel Zannou, Michel Alary

Centre hospitalier affilié universitaire de Québec, Hôpital du Saint-Sacrement, Québec, Québec, Canada


Addendum to abstract of published article (Conclusions): To be effective on HIV and STI risk reduction, all components of preventive interventions targeting FSW should be integrated. Such interventions should be urgently scaled up in all countries where FSW contribute disproportionately to the spread of HIV.

See online Appendix O-13 for PowerPoint presentation.
O-14  Acceptability of safe male circumcision among HIV high-risk fishing communities along Lake Victoria: a qualitative study
Simon Sigirenda, Juliet Mpendo, Noah Kiwanuka
Uganda Virus Research Institute – International AIDS Vaccine Initiative (UVRI–IAVI) HIV Vaccine Program, Kampala, Uganda
Recent studies in fishing communities of Uganda have shown high HIV rates (prevalence of 23–35% and incidence of 5/100 person years of observation) with disproportionately very low prevention and care services in these hard-to-reach communities. Safe male circumcision (SMC) has been shown to be both efficacious and effective in preventing HIV acquisition. Fishing communities form one of the high high-risk groups that are among the key drivers of the epidemic. This study assessed the acceptability of SMC as a proven HIV prevention tool. Key informant interviews and 11 focus group discussions were conducted. Willingness to circumcise was high and the common source of circumcision information was radio and interactions with health workers. Most women interviewed were willing to support their partners to undergo SMC. Uptake of SMC is militated by financial constraints (i.e., missing work due to the healing period.) Acceptability of SMC is high in fishing communities since it provides an opportunity that could reduce community members’ vulnerability to HIV infections. Acceptability was found to be high in part because of the communities’ awareness of the impact HIV/AIDS has had on them. Therefore, health service providers need to innovatively integrate SMC in their work, by ensuring that the service is available at an affordable cost.
See online Appendix O-14 for PowerPoint presentation.

O-15  Family planning use and associated factors among women enrolling into HIV care, southwestern Uganda
Winnie Muyindike, Robin Fatch, Nneka Emenyonu, Judith A. Hahn
Mbarara University of Science and Technology, Mbarara, Uganda
Background: Preventing unwanted pregnancies among people living with HIV is an important component of prevention of mother to child HIV transmission (PMTCT) and contributes to reduced maternal morbidity and mortality. However, there are few data on the frequency and methods of contraceptives used by HIV-positive females enrolling into HIV care. PMTCT has not yet fully harnessed from the Family Planning (FP) strategy.
Methods: This was a retrospective study of electronic medical records from female patients’ initial visits in 2009 to a semi-rural HIV clinic in southwestern Uganda. We conducted bivariate and multivariate logistic regression to examine associations between reported contraceptive use and clients’ demographic, biological and social behavioral predictors including HIV status disclosure to sexual partner(s).
Results: Of the 1036 females of reproductive age (18–49 years), 826 sexually active, non-pregnant women at enrollment were included in this analysis. The proportion of HIV-positive females reporting FP use at enrollment into the clinic was 27.8%. The most common method used was injectable hormones (51.7%), followed by condoms (29.6%) and oral contraceptives (8.7%). Very few clients reported using dual methods (2.2%), implants, natural methods or sterilization methods. Use of highly effective methods (hormonal methods, intrauterine devices or sterilization) was reported for only 18.2%. In multivariate analysis, the odds of contraceptive use were significantly higher among women with a secondary education (odds ratio [OR] 1.71, 95% confidence interval [CI] 1.09–2.68), monthly income over 250,000 Ugandan shillings (OR 5.54, 95% CI 1.63–18.20) or three or more children (OR 4.33, 95% CI 1.35–12.11). Compared to women aged 18–24 years, 36- to 49-year-old women had decreased odds of reporting contraceptive use (OR 0.47, 95% CI 0.27–0.83). There were no significant independent associations between HIV status disclosure to spouse, or partner HIV status and contraceptive use.
Discussion: The use of contraception among HIV-positive females entering HIV care in southwestern Uganda is low. Our results suggest that while there is a need to focus on contraceptive use dissemination for everyone of reproductive age, increased emphasis should be given to those with lower education and income levels. HIV clinics may be prime sites for contraceptive use dissemination and integration.
See online Appendix O-15 for PowerPoint presentation.

O-16  Male involvement in prevention programmes of mother-to-child transmission of HIV: a systematic review to identify barriers and facilitators
Frederick Morfaw, Lawrence Mbuagbaw, Ana-Paula Wunderlich, Lehana Thabane, Phili Nana, Clarissa Rodrigues, John Kunda
University of Yaoundé I, Yaoundé, Cameroon
Background: Many reports point towards the beneficial effect of male partner involvement in programmes for the prevention of mother-to-child transmission (PMTCT) of HIV.
Objectives: This paper summarises the barriers and facilitators of male involvement in PMTCT of HIV.
Methods: We searched PubMed, Embase, CINAHL and the Cochrane Central Register of Controlled Trials (CENTRAL) for articles published in English from 1998 to March 2012. We included studies conducted in a context of antenatal care or PMTCT of HIV reporting male actions that affected female uptake of PMTCT services.

Results: We identified 24 studies from peer-reviewed journals: 21 from sub-Saharan Africa, two from Asia and one from Europe. Barriers to male PMTCT involvement were mainly at the level of the society, the health system and the individual. The most pertinent was the societal perception of antenatal care and PMTCT as a woman’s activity, and it was unacceptable for men to be involved. Health system factors such as long waiting times at the antenatal care clinic and the male unfriendliness of PMTCT services were also identified. Lack of communication within the couple, the reluctance of men to learn their HIV status, the misconception by men that their spouse’s HIV status was a proxy of theirs, and the unwillingness of women to get their partners involved due to fear of domestic violence, stigmatization or divorce were among the individual factors. Actions shown to facilitate male PMTCT involvement were either health system actions or factors directly tied with the individuals. Inviting men to the hospital for voluntary counselling and testing of HIV and offering PMTCT services to men at sites other than antenatal care were key health system facilitators. Prior knowledge of HIV and prior male HIV testing facilitated their involvement. Financial dependence of women was key to facilitating spousal involvement.

Conclusions: There is a need for health system amendments and context-specific adaptations of public policy on PMTCT services to break down the barriers to, and facilitate male involvement in, PMTCT. The way forward is to develop a tool for measuring male partner involvement in PMTCT at the societal level—the SAMP (Scale Assessing Male participation in PMTCT).

See online Appendix O-16 for PowerPoint presentation.

O-17 “Coming to fetch AIDS”: research participants talk about misconceptions and stories about HIV/AIDS and HIV vaccines among community members

Anthea Lesch, Leslie Swartz, Surita Roux

Stellenbosch University, Stellenbosch, South Africa, and Desmond Tutu HIV Foundation

Introduction: Communities form an integral part of the development of new HIV prevention technologies. Without their buy-in, support and participation in clinical trials, success in developing an efficacious HIV vaccine is unlikely. Clinical trials involve much that is beneficial to individuals and communities who participate in such trials. Research shows that participants experience their participation in HIV vaccine research as empowering and beneficial as it improves their quality of life by motivating them to engage in health protective behaviours. It is not clear, however, how research participation is viewed at the community level. Community engagement staff members at HIV vaccine research centres in communities being targeted for participation in HIV vaccine research invest a great deal of effort in educating community members about HIV/AIDS and HIV vaccines. The aim of their activities is to stimulate community members’ interest in the research and provide them with information that can serve as the basis for informed decision-making with respect to research participation. Recruiting participants into studies, however, remains a challenge. The aim of the research was, therefore, to gain insight into the dialogue about HIV/AIDS and HIV vaccines among community members who are being targeted for their participation in HIV vaccine research.

Method: The research was conducted at a research centre in a peri-urban community in the Western Cape Province of South Africa at which various HIV prevention trials are being conducted. Purposive sampling was used to recruit community members who had participated in community education and awareness-raising activities at the research centre. A total of 24 participants participated in the research. Data were collected using a series of four focus group discussions. Data were analysed using thematic analysis. Ethical approval for the conduct of the research was granted by the relevant ethical review boards. Participants provided informed consent and were provided with a transport reimbursement.

Results: The research participants described the dialogue about HIV/AIDS and HIV vaccines among their friends, family members and other members of their communities as being characterised by fear, mistrust and avoidance of the disease and anything related to it. They speculated that this avoidance stems from a lack of knowledge about HIV/AIDS and HIV vaccines as they felt that there is not enough information about HIV/AIDS and HIV vaccines available to people in their communities. They reported that misconceptions and stories about the research centre, people who visit the research centre and HIV vaccine research and research-related procedures prevail among community members. Given its association with HIV/AIDS, community members are sceptical about the research centre and the research being conducted. The predominant misconception reported in this regard is that researchers at the research centre are injecting research participants with HIV. Community members also hold misconceptions about people who visit the research centre, believing that they are HIV positive and are being used as guinea pigs. In addition, community members who visited the centre but chose not to participate in the research held an attitude of
Thus, community members who had undergone screening procedures view the process with mistrust and avoid returning for further visits. Fear of needles and scepticism about the purpose of the blood draws were cited as objections among these community members.

Conclusion: The results illustrate that misconceptions and stories about HIV/AIDS and the HIV vaccines are prevalent in the community and are maintained by the dialogue among community members. This dialogue fuels fear and avoidance of the research centre, people who participate in HIV vaccine research and the research process and associated procedures. The current dialogue about HIV/AIDS and HIV vaccines in the community is, therefore, one that inhibits research participation. We know, however, that at the individual level, participation in the research being conducted at the research centre is experienced as empowering and beneficial. We can harness the benefits of the individual-level experience as the foundation for building a “science of community engagement” in order to create a dialogue about HIV/AIDS and HIV vaccines that is experienced as empowering and beneficial by the community as a whole. Creating safe social spaces for dialogue about HIV/AIDS in the community may prove to be highly beneficial in dispelling the misconceptions and stories about HIV/AIDS and HIV vaccines that impede community participation in the research process.

See online Appendix O-17 for PowerPoint presentation.

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Structural and operational issues

**O-18 Building capacities of elected national representatives to interpret and to use evidence for health-related policy decisions: a case study from Botswana**

Neil Andersson, Mokgweetsi Masisi, Lehana Thabane, Anne Cockcroft

CIET, Gaborone, Botswana; Government of Botswana, Gaborone, Botswana; McMaster University, Hamilton, Ontario, Canada

Background: Elected national representatives debate, make decisions, and allocate funds but may lack the skills to interpret evidence on HIV and other health-related topics. Training offered for members of parliament (MPs) usually covers the mechanics and ethics of their roles, while training in use of evidence is aimed at technical officer grades. At the request of the Government of Botswana, in 2011 we surveyed MPs about their need for evidence and for training in the use of epidemiological evidence, particularly in the field of HIV prevention research. Guided by their responses, in November 2011 we conducted a two-day training workshop for MPs and ministers, and we built on this in a further two-day workshop in November 2012 (Fig. O-18-1).

Methods: Research assistants interviewed the MPs face to face or on the telephone. The 2011 workshop covered the language of evidence, types of evidence for planning, evidence gaps and how to fill them, and questions to probe the quality of evidence. The 24 participants, including four ministers, learnt the role of counterfactual evidence, the policy importance of the number needed to treat, and the role of unit costs in choosing the most effective mix of interventions, for example to tackle the HIV epidemic. They considered the value and limitations for planning of several examples of published evidence related to HIV prevention. The 2012 workshop again covered issues of counterfactual evidence and the types of evidence most useful for planning. It focused on the need to reduce the continuing 15% HIV annual incidence in Botswana; this translates to about 14,000 new HIV infections each year, particularly among young women who are at risk from transactional sex with older men. Increased HIV prevention investment is needed, but this should be channelled into programmes that evidence suggests can be most effective; an evidence-based investment modelling tool could help to achieve maximum impact from prevention investment. The parliamentarians discussed potential local strategies for reducing new HIV infections and how to measure the impact of such strategies.

Results: Of the 57 elected representatives, 27 completed an interview in 2011. They (25) reported the need to use evidence in their work but said they lacked good quality, timely evidence...
They struggled with jargon and technical wording and lacked access to up-to-date evidence. Nearly all felt they could benefit from training in interpreting and using evidence to support decision-making: “decisions would be based on facts.” The two workshops together covered some 36 MPs, including seven ministers, the deputy speaker, the leader of the Opposition, and the chair of the parliamentary health and HIV/AIDS committee. This represents more than half the MPs in the country. In the 2011 workshop, participants successfully identified strengths and weaknesses of examples of published evidence. Participants in 2012 proposed approaches to reducing new HIV infections including the following: MPs could be exemplars and champions of prevention, the national poverty eradication programme could target young women in particular, community discussions of “morality” could be held, sessions could be offered for school children, and traditional leaders could be involved. Participants in both the workshops were active and engaged. They evaluated the training positively. We will attempt to track the use of evidence in parliamentary business.

Conclusions: The training was well received by MPs in Botswana. Several factors contributed to this. The timing was right (the debate about the national AIDS policy), there was a strong ministerial champion, we sought and incorporated needs of the MPs, the content was direct and relevant, and Botswana is a peaceful country with a functional parliament. It may be possible to use the experience in Botswana to extend similar training in other countries in the region to support evidence-based efforts to tackle the HIV epidemic.

See online Appendix O-18 for PowerPoint presentation.

0-19 Expansion of couples’ voluntary counseling and testing in the Copperbelt Province in Zambia: an examination of the distribution of HIV serostatus within the province

Carolina Kwok, Mubiana Inambao, William Kilembe, Tyronza Sharkey, Phillippa Chadd, Naeemah Munir, KaeAnne Parris, Julie Pulerwitz, Ibou Thior, Joseph Abdallah, Wan-Hsuan Kuo, Amanda Tichacek, Susan Allen

Zambia–Emory HIV Research Group, Ndola, Zambia

Background: Zambia has a population of over 13 million people, with an HIV prevalence of approximately 15% in cohabitating partners. Seventy percent of HIV infections are acquired from discordant cohabiting partners, yet less than 1% of those couples have been tested together. Fifteen to twenty percent of couples counseled and tested at couples’ voluntary counseling and testing centers in Zambia have discordant results. Previous studies in Zambia have estimated that scale-up of couples’ voluntary counseling and testing (CVCT) services can reduce heterosexual HIV transmission in sero-discordant couples by 35%–80%. The Zambia–Emory HIV Research Group (ZEHRP) has been offering CVCT services in Lusaka, Zambia, since 1994. In 2004, ZEHRP started offering services in the Copperbelt, the second most densely populated province in Zambia. In October 2010, ZEHRP started expansion of CVCT services to 60 government and private mine clinics in collaboration with PATH through the Arise program, funded by the Canadian International Development Agency. The goal of the expansion is to test 68,000 couples (approximately 15% of the population in the province) over 30 months in order to establish CVCT as a standard of care in the Copperbelt Province.

Methods: ZEHRP received permission from the Ministry of Health and the Provincial Office in September 2010 to launch the project and the expansion started in October 2010. ZEHRP assists the government and mine clinics in implementing CVCT services by providing training to health care providers working in the selected clinics in all districts in operation: Ndola, Kitwe, Chingola and Luanshya. Promotion agents are also trained by ZEHRP to sensitize the communities about CVCT and encourage couples to test together at the clinics. The training manuals can be found at http://www.cdc.gov/globalaids/resources/prevention/chct.html. ZEHRP collaborates with the District Health Management Teams in all areas of implementation, including identifying personnel to be trained and supply provision. Weekend service was chosen to minimize clinic disruption and impact on work schedules for the couples. Since early 2012, attempts to integrate CVCT into other services such as antenatal clinics and under-5 clinics have also proven successful. Health-care providers record all test results in anonymous logbooks collected by ZEHRP, to monitor serostatus distributions and seroconversion rates within the districts. Couples attending CVCT are given a unique ID and are provided appropriate referrals within the government clinics as required. Data collected are quality controlled at the clinic, at the main research site in Ndola and at the home office at Emory University in Atlanta, Georgia, USA.

Results: As of November 2012, 25 months into the expansion, ZEHRP has launched CVCT services in 52 clinics and has tested 54,498 couples since project initiation (Fig. 0-19-1). Of the couples tested, less than 10% were previously tested together for HIV. The results demonstrate that the HIV serodiscordance in couples in the Copperbelt is slightly lower than the national prevalence, 9% compared to the national average of 12%. However, the sample is only drawn from 4 districts and is not representative of the entire province, which has 10 districts. Approximately 94% of all couples tested are in cohabitating relationships. In the Copperbelt, the distribution is 16% for concordant positive (M+F+), 9% for discordant (4% M–F+, 5% M+F–) and 75% for concordant negative.
(M–F–). The pattern of a higher proportion of M–F+ couples is consistent throughout the districts (Fig. O-19-2). In pregnant women who test with their partners there is no clear trend in the HIV serostatus distribution although there is a larger proportion of women in M+F– relationships in Ndola compared to the other districts. The largest proportion of females in discordant relationships is in women between the ages of 21 and 30 years old whereas for males, the age range is between 25 and 40 years old; similar patterns are found in all districts.

**Conclusion:** The current project in the Copperbelt has shown that the rapid expansion of CVCT services in government clinics is a feasible endeavor with close collaboration with all stakeholders. Previous studies have demonstrated similar patterns of higher prevalence of positive women in discordant couples and the current results show that women at peak reproductive ages, between 21 and 30 years old, represent the largest demographic found in discordant couples along with men between 25 and 40 years old. Identifying such trends can inform ZEHRP on how to tailor CVCT services to specific groups, such as offering voluntary medical male circumcision to HIV-negative males in discordant relationships and education on condom use negotiation for younger at-risk females. These findings affirm the importance of CVCT; identification of discordant couples is integral to HIV prevention strategies in Zambia as the majority of infections occur between cohabitating heterosexual couples.

See online Appendix O-19 for PowerPoint presentation.

**O-20 Discordant couples cohort is still relevant for HIV vaccine studies despite low transmission rates: Canadian–Nigerian experience**

Sophia Osawe, Evaezi Okpokoro, Ruth Datiri, Grace Choji, Felicia Okolo, Pam Datong, Alash’le Abimiku

Plateau State Human Virology Research Centre, Jos, Nigeria; Institute of Human Virology, Abuja Nigeria; Institute of Human Virology, School of Medicine, University of Maryland, Baltimore, Maryland, USA
Background: As HIV/AIDS continues to be a global health problem, especially in Africa, it is critical to get an effective vaccine. Antiretroviral treatment continues to have challenges associated with adherence, irregular supply of antiretroviral drugs and lack of monitoring tests. Studies have established that a majority of new HIV transmissions occur among heterosexual sero-discordant couples in sub-Saharan Africa. Discordant couples have been known to be a medium-risk group for HIV transmission. This group is suitable for HIV vaccine trials and/or for understanding immune responses in HIV-exposed but uninfected individuals who are subsequently vaccinated because of their natural exposure and high retention rates recorded in the past. A cohort of discordant couples is being developed in Jos, Nigeria, at the Plateau State Human Virology Research Centre. This cohort is being developed and followed up to record HIV incidence, sexually transmitted infections, retention rates and risk factors. The study will help prepare grounds for future vaccine trials through the characterization of the cohort and training of research site staff. The data collected from this cohort will establish baseline information on the general Nigerian population and the next steps for an HIV experimental vaccine trial and its interpretation.

Method: A prospective observational cohort study to enroll 500 HIV sero-discordant couples with a 2-year follow-up was established in Jos, Nigeria. There are a total of 11 visits to be spread across 2 years. Relevant ethical approvals from 3 local and international ethical committees were obtained. Volunteers were screened at the research site in Jos and four other satellite sites clustered around the research site. Screening was done using eligibility criteria and informed consent was provided by all eligible volunteers. Standardized questionnaires were used and clinical examinations performed at both the research site and the satellite site to maintain conformity. Laboratory tests performed included serology tests (HIV, syphilis), complete blood counts and liver and kidney function tests. HIV sero-positive partners were not enrolled into the study but they were invited to support their partners enrolled in the study during couples counseling. CD4 counts and viral loads were performed for the sero-positive partners as part of their care and as an incentive since viral load is not routinely performed in this setting. All data were collected on Teleform-designed forms and were extracted into an Access database for analysis using Stata.

Results: A total of 545 HIV-negative volunteers have been enrolled into this cohort; however, analysis was done on only 315 enrollees who had a minimum of 3 follow-up visits. The cohort had an equal distribution of males and females, 157 (49.8%) females and 158 (50.2%) males, with a mean age of 38 years. Analysis of condom use showed that 127 enrollees (40.3%) reported use of condoms at all times while 107 (34.0%) reported non-frequent use and 81 (25.7%) never used condoms (Table O-20-1). Among the HIV-positive partners, 94.3% were already on antiretroviral treatment at various sites supported by the U.S. President’s Emergency Plan for AIDS Relief (Table O-20-2). The average CD4 count was 450 cells/µL (standard deviation ± 283 cells/µL) (Table O-20-2). Most importantly, 113 (71%) of the HIV-positive partners had detectable viral load levels despite being on highly active antiretroviral therapy for an average of 5 years. A quarter of those with detectable viral loads had viral loads above 10,000 copies/mL (range >10,000 to 1,638,427 copies/mL) (Table O-20-2). Two of the 315 HIV-negative volunteers seroconverted, giving this cohort an incidence of 0.6%. The viral loads of the HIV-positive partners of those who seroconverted were low at 3,200 and 4,320 copies/mL. Further analysis will be required to determine if these sero-negative participants were infected by their HIV-positive partners. Sixteen (5.1%) of the HIV-negative volunteers reported that their partners have been previously or recently diagnosed with an STI. We documented a total of 4 volunteers testing positive for syphilis (3.1%).

Conclusion: The recorded HIV incidence in the cohort is 0.6%, which is lower than that desirable for HIV vaccine trials. However, our analysis was performed only on two thirds of the cohort as stated above and the cohort was only followed for a maximum of 7 months. Our study indicates that despite the availability of antiretroviral therapy, sero-negative partners continue to be at risk of being infected by their HIV-positive partners in resource-limited settings as demonstrated by > 10,000 viral load copies in a quarter of the HIV-positive partners who were tested. The counseling team was involved in couples and risk-reduction

<table>
<thead>
<tr>
<th>Condom use</th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>57</td>
<td>70</td>
<td>127</td>
<td>40.3</td>
</tr>
<tr>
<td>Never</td>
<td>34</td>
<td>47</td>
<td>81</td>
<td>25.7</td>
</tr>
<tr>
<td>Sometimes</td>
<td>66</td>
<td>41</td>
<td>107</td>
<td>34.0</td>
</tr>
<tr>
<td>Total</td>
<td>157</td>
<td>158</td>
<td>315</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table O-20-1: Condom use in the cohort

<table>
<thead>
<tr>
<th>Gender</th>
<th>No. of HIV-seropositive partners</th>
<th>No. on antiretrovirals</th>
<th>Mean CD4 count (cells/µL)</th>
<th>No. with &lt; 10,000 copies/mL</th>
<th>No. with &gt; 10,000 to 1,638,427 copies/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>131</td>
<td>125</td>
<td>467</td>
<td>69</td>
<td>28</td>
</tr>
<tr>
<td>Male</td>
<td>114</td>
<td>106</td>
<td>394</td>
<td>75</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>245</td>
<td>231 (94.3%)</td>
<td>450</td>
<td>134 (74.9%)</td>
<td>45 (25.1%)</td>
</tr>
</tbody>
</table>

Table O-20-2: CD4 counts and viral loads of HIV-seropositive partners
counseling; however, lack of or inconsistent use of condoms was reported by the enrollees. This fairly healthy sero-discordant couple cohort is an important natural adult model to study transmission, immune response in HIV-exposed adults and effectiveness of candidate HIV vaccines.

See online Appendix O-20 for PowerPoint presentation.

O-21 Volunteers’ perceptions and experiences of clinical research participation in Kenya: case study of the Kenya AIDS Vaccine Initiative (KAVI)

Emily Nyariki, Joyce Olenja, Robert Lorway, Omu Anzala

Kenya AIDS Vaccine Initiative (KAVI), Department of Medical Microbiology, and School of Public Health, University of Nairobi, Nairobi, Kenya; Department of Community Health, University of Manitoba, Winnipeg, Manitoba, Canada

Background: AIDS remains a leading cause of mortality in sub-Saharan Africa, accounting for almost half of the world’s HIV-related deaths. With this in mind, a number of primary prevention interventions have been adopted across the globe, including voluntary medical male circumcision, prevention of mother-to-child transmission and pre-exposure prophylaxis, which are currently in use in Kenya. While these strategies have helped slow the spread of the epidemic, there is a need to search for a more conclusive avenue to avert the epidemic, and this requires not only a comprehensive approach that can tackle the multifaceted factors that have contributed to the spread of the disease but also an HIV vaccine. For the last two and half decades there have been efforts to develop HIV vaccines. The conduct of clinical research faces unique challenges that compromise optimal recruitment of volunteers into studies. In Kenya, at the Kenya AIDS Vaccine Initiative (KAVI), where a number of clinical research studies are being conducted, data from the recruitment sites reveal that some eligible volunteers fail to turn up for actual enrollment even after providing consent to participate. Questions regarding volunteers’ knowledge, understanding, and attitudes towards clinical research and how their experiences of participation affect their decision making have been raised. Understanding participants’ perceptions of their research experiences provides a valuable measure of ethical treatment, yet no validated instruments exist to measure these experiences. Additionally, few studies have attempted to assess the quality and efficacy of the entire clinical research process from the subject’s perspective. This study aims at exploring volunteers’ perceptions and experiences and their potential impact on decision making to participate in clinical research. Specifically the study will attempt to (i) establish the characteristics of individuals who participate in clinical research studies, (ii) establish volunteers’ perceptions towards clinical research, (iii) establish volunteers’ experiences at various stages of clinical research and (iv) identify factors that enhance/constrain volunteers’ clinical research participation experience.

Methods: This research will employ a mixed-method design to examine how volunteers’ experiences and perceptions of research participation are likely to impact on their willingness and decision making to participate. A sequential transformative strategy will be adopted for data collection where a survey questionnaire will be administered to 233 participants to be drawn from past and ongoing KAVI clinical trials that will include 2 vaccine trials, 1 drug trial, and 2 observational studies. Thirty-five in-depth interviews will be conducted with participants to be purposively selected from the 233 participants, and 8 key informant interviews will be conducted with clinical staff. Quantitative data will be coded and analysed using SPSS while qualitative data will be coded and analysed using Atlas.ti.

Expected outcomes: It is anticipated that findings from this study will inform the design of future clinical research studies, in order to enhance volunteer experiences of participation, including research literacy among local communities and volunteer recruitment and retention in clinical research. It is further anticipated that understanding factors that hinder potential volunteers from participating in clinical research will aid in identifying potential recruitment strategies and volunteer information needs.

See online Appendix O-21 for PowerPoint presentation.

O-22 Building capacity to design, implement and evaluate action research projects to decrease the burden of HIV and tuberculosis in the healthcare workforce: a South African – Canadian collaboration


Global Health Research Program, University of British Columbia, Vancouver, British Columbia, Canada; Centre for Health Systems Research and Development, University of the Free State, Bloemfontein, South Africa; Vancouver Coastal Health, Vancouver, British Columbia, Canada; National Institute for Occupational Health, Johannesburg, South Africa; Occupational Health Unit, Department of Community Health, Bloemfontein, South Africa

Objectives: South Africa is buckling under an HIV and tuberculosis (TB) co-epidemic, which poses high risks to healthcare workers (HCWs). International guidelines have been endorsed to improve access of HCWs to HIV and TB prevention and care, and there is some, albeit limited, evidence that workplace-based
Therefore, following some initial training a one-year certificate programme participants groups. Each group was assigned Canadian and South African TB = tuberculosis. conducted by certificate programme participants Table O-22-1: Workplace HIV and TB research projects conducted by certificate programme participants

<table>
<thead>
<tr>
<th>Group</th>
<th>Research topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Improving utilisation of workplace HIV/AIDS programme for healthcare workers at hospital A</td>
</tr>
<tr>
<td>2, 3</td>
<td>Reducing the risk of supporters of directly observed therapy acquiring TB during home visits in Bloemfontein and Welkom</td>
</tr>
<tr>
<td>4</td>
<td>Creating a safe environment for patients and staff in the bronchoscopy theatre at hospital B</td>
</tr>
<tr>
<td>5</td>
<td>Investigating TB infection control practices in the medical outpatient department at hospital A</td>
</tr>
<tr>
<td>6</td>
<td>Improving reporting of blood and body fluid exposures in the workplace in a district hospital</td>
</tr>
<tr>
<td>7</td>
<td>Establishing an effective system to prevent, identify and treat TB in employees at hospital B</td>
</tr>
<tr>
<td>8</td>
<td>Improving infection control and safety practices in the central laundry: baseline assessment, intervention and evaluation</td>
</tr>
</tbody>
</table>

TB = tuberculosis.

programs show promise. However, building capacity in occupational health (OH) and infection control (IC) in the healthcare sector is necessary for such guidelines to be implemented. Therefore, following some initial training a 1-year certificate programme was developed to improve capacity to conduct and evaluate workplace-based HIV and TB prevention interventions and to better empower HCWs to serve as “agents of change” within high-risk workplaces. To accommodate busy schedules, the programme, which ran from April 2011 to May 2012, adopted a community-based learning approach comprising 4-day face-to-face modules and a group research project. This article discusses its successes and challenges.

Methods: Thirty-one participants (81% female) with responsibility for HIV and/or TB prevention in their healthcare workplaces were enrolled in this programme. The participants, including mostly OH nurses, IC practitioners and health managers, formed 8 groups. Each group was assigned Canadian and South African mentors and was required to conduct research projects aimed at improving OH and IC in their workplaces. An occupational health and safety information system (OHASIS) was developed to assist in data management. A comprehensive programme evaluation was conducted using quantitative and qualitative methods to assess changes in knowledge, attitudes, skills and practices related to the modules and the projects conducted. This included 6 questionnaires respectively administered before and after each of the modules, 3 sets of individual interviews, participant observations and an evaluation of the group projects. Additionally, actual knowledge was assessed using true/false questions and reactions were captured using open-ended questions.

Results: The 8 projects covered a range of topics (Table O-22-1) and yielded some important findings (Table O-22-2).

Table O-22-2: Key findings and/or recommendations from the group projects

<table>
<thead>
<tr>
<th>Group</th>
<th>Most important findings and/or recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Confidentiality must be guaranteed to improve utilisation of OH clinic for HIV/TB care</td>
</tr>
<tr>
<td></td>
<td>Workplace stigma must be addressed through more training workshops and support groups</td>
</tr>
<tr>
<td>2, 3</td>
<td>Training did lead to overall improvement in levels of TB knowledge, attitudes and beliefs</td>
</tr>
<tr>
<td></td>
<td>Administrative controls and use of personal protective equipment were lacking</td>
</tr>
<tr>
<td></td>
<td>Health and safety problems were reported to coordinators but not followed up</td>
</tr>
<tr>
<td>4</td>
<td>Infection control compliance improved from 46% to 83% following training</td>
</tr>
<tr>
<td></td>
<td>Environmental risks identified included overcrowding, poor ventilation, lack of hand-washing supplies and cluttered surfaces</td>
</tr>
<tr>
<td>5</td>
<td>Only 24% of HCWs reported that they are screened annually for TB</td>
</tr>
<tr>
<td></td>
<td>47% correctly answered questions related to personal protective equipment</td>
</tr>
<tr>
<td>6</td>
<td>9/10 respondents reported having had a needle-stick injury</td>
</tr>
<tr>
<td></td>
<td>Exposures were significantly greater for HCWs with less than 6 years of work experience</td>
</tr>
<tr>
<td></td>
<td>Risks were greater in casualty, maternity and male wards</td>
</tr>
<tr>
<td>7</td>
<td>Workplace intervention led to an increase in utilisation of the OH clinic for HIV and TB services</td>
</tr>
<tr>
<td></td>
<td>Confidentiality was identified as a barrier</td>
</tr>
<tr>
<td>8</td>
<td>Only 85% reported having had hepatitis B vaccination</td>
</tr>
<tr>
<td></td>
<td>90% reported that no training was received on needle-stick injury prevention</td>
</tr>
<tr>
<td></td>
<td>While 82% knew how to contact the health and safety representative, only 56% reported doing so</td>
</tr>
</tbody>
</table>

HCW = healthcare worker, OH = occupational health, TB = tuberculosis.

Questionnaire results indicated a significant increase in how participants rated their skills before versus after the programme (179% improvement; p = 0.001). A 9.2% improvement in self-rated knowledge was also demonstrated, corroborated by actual knowledge increases (68.5% to 75.6%). Self-rated attitude scores were very high at the onset (92.5%) and did not significantly change. Baseline questionnaire results showed that participants scored particularly low in data management skills (61.3%), knowledge of guidelines (49.1%) and knowledge and skills related to research methods (47.2%) (Table O-22-3). At the conclusion of the programme, scores had considerably increased, ranging from 67.1% in the case of guidelines to 92.5% for HIV knowledge items. Self-rated knowledge and skills scores were at their highest in the mid-term evaluation and decreased slightly at the post-programme questionnaire. As an educational tool, the projects were very successful; participants reported that experiencing the process of designing, implementing and evaluating an
Some participants report being "intimidated" by the research process. Some participants reported having used the Google search engine for the first time; others began upgrading HIV and TB resources in their workplace. One participant explained that it "empowered me a lot and I can even advise my colleagues when I see them not using PPE [personal protective equipment] properly." The projects documented health and safety hazards, particularly related to IC, and offered strategies to remedy these. Results presented to decision-makers and other stakeholders led to measures being taken to address concerns.

**Lessons learned and recommendations:** Overall, the programme was successful in empowering participants with knowledge and skills necessary for improving their working conditions. The slight dip in scores from the mid to final evaluation questionnaires suggests that participants may have realized that although they acquired new skills and knowledge, there is much more they still had to learn. Promisingly, participants not only reported that they were empowered by an increase in their confidence but also an increase in their capacity to seek and find the information they require. On the other hand, considerable mentor involvement was needed; many participants were inexperienced and lacked research skills. As such, similar programmes may wish to set entry requirements if participants are expected to be able to autonomously conduct and evaluate interventions during, or even after, programme completion. Implementing data management systems was also challenging. Nonetheless, the effort was worthwhile. The programme also helped prepare participants for a randomized trial of a comprehensive intervention to improve HIV and TB services for HCWs, now underway.

We conclude that international collaboration to train OH and IC practitioners and improve information management is useful to address operational needs and help initiate needed research. See online Appendix O-22 for PowerPoint presentation.

### Table O-22-3: Knowledge and skills pre-programme, mid-programme (after the first module) and post-programme

<table>
<thead>
<tr>
<th>Question category</th>
<th>Pre-programme</th>
<th>Mid-programme</th>
<th>Post-programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data management skills</td>
<td>61.3 (11.8)</td>
<td>74.0 (12.2)</td>
<td>68.8 (18.8)</td>
</tr>
<tr>
<td>Occupational health and infection control knowledge and skills</td>
<td>73.1 (21.2)</td>
<td>87.7 (14.5)</td>
<td>82.1 (11.4)</td>
</tr>
<tr>
<td>HIV knowledge</td>
<td>83.8 (15.6)</td>
<td>94.7 (9.0)</td>
<td>92.5 (11.5)</td>
</tr>
<tr>
<td>TB knowledge</td>
<td>66.6 (21.1)</td>
<td>92.0 (10.0)</td>
<td>83.3 (18.3)</td>
</tr>
<tr>
<td>Knowledge on guidelines related to HIV and TB in the healthcare workplace</td>
<td>49.1 (22.6)</td>
<td>77.0 (18.6)</td>
<td>67.1 (18.5)</td>
</tr>
<tr>
<td>Research methods knowledge and skills</td>
<td>47.2 (21.4)</td>
<td>75.0 (17.2)</td>
<td>68.8 (18.0)</td>
</tr>
<tr>
<td>Policy and legislation knowledge</td>
<td>62.5 (23.7)</td>
<td>82.7 (14.6)</td>
<td>73.3 (18.3)</td>
</tr>
</tbody>
</table>

SD = standard deviation, TB = tuberculosis.

*Scores are based on the median answers from the Likert questions with possible answers ranging from 1 to 5.

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**O-23 Building capacity for HIV prevention research in developing countries through a Canadian–African partnership: a case study of The AIDS Support Organization (TASO) Uganda**

Josephine Birungi, Sarah Khanakwa, Edward Mills, Catherine Muldoon, David Moore, Kate Shannon, Christine Nabiryo

The AIDS Support Organisation (TASO), Kampala, Uganda

**Background:** The AIDS Support Organization (TASO) is one of the largest indigenous non-governmental organizations in Africa, providing care to over 90,000 HIV-positive persons in Uganda. TASO recognized the inadequate capacity to conduct research as documented in TASO's strategic plan of 2008–2012, and therefore filling this gap was prioritized during 2008–2012. Through partnership with the Canada–Africa Prevention Trials Network (CAPT-N), TASO has progressively built capacity to conduct research and to disseminate findings that have later been ploughed back to strengthen TASO's programming.

**Methods:** We conducted research capacity building workshops for TASO staff at least biannually. These workshops were facilitated by a team of researchers from Canada and Ugandan counterparts from the Uganda National Council for Science and Technology (UNCST) and Makerere University. Topics addressed included research-proposal writing, manuscript and abstract writing, and analysis of qualitative and quantitative data. Junior Ugandan researchers were supported to conduct HIV prevention research projects under the supervision of more senior Canadian investigators. Mentorships and academic scholarships to pursue master's degrees have been awarded to staff at TASO on a competitive basis. Computers, relevant literature, and other equipment have been provided to support the TASO teams.

**Results:** A 3-year research project has been successfully conducted to completion looking at antiretroviral therapy as...
Abuja, Nigeria; National Agency for Food and Drug Administration and Control, NAFDAC) created an excellent opportunity to develop in-country capacity for HIV vaccine clinical trials according to the national HIV vaccine plan. Thus, in collaboration with the University of Ottawa, three regulatory bodies involved in HIV, research ethics and vaccine licensure (the National Agency for the Control of AIDS, NACA; the National Health Research Ethics Committee, NHREC; and the National Agency for Food and Drug Administration Control, NAFDAC) were identified for training and mentoring. Gap analysis indicated the need for training in ethics, regulation and monitoring of clinical trials, etc. Officers from these agencies were involved early in the grant proposal stage and in the contractual agreement following grant offer. Thereafter, senior and mid-level officers from these agencies were identified for the purpose of training, routine meetings with the research team as well as a site base visit. This has been pivotal in sustaining commitment and participatory oversight over the past 18 months.

**Results:** During this period, eight trainees from NACA, NHREC, NAFDAC and the research team completed training on statistical methods and epidemiology at the Institute of Human Virology in Nigeria (IHVN), which has reinforced their understanding of the scientific basis of the ongoing sero-discordant study. Three trainees attended an introductory course on clinical trials at IHVN and 12 trainees attended a site base research ethics workshop supervised by NHREC and successfully attained a certificate in good clinical laboratory practice (Table O-24-1). Courses taught included international ethical guidelines for biomedical research involving human subjects, research ethics regulation in Nigeria (i.e., highlights of the national code for health research ethics), ethical issues in clinical trials, the informed consent process, research misconduct, etc. These have strengthened the ethical values of the research team as well as those of the officers of

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**O-24 Involving national coordinating, regulatory and ethical bodies in HIV vaccine preparedness in Nigeria: the Canadian–Nigerian collaboration experience**

_Evaezi Okpokoro, Sophia Osawe, Pam Datong, Aminu Yakubu, Paul Orhii, John Idoko, Gary Garber, Alash’le Abimiku_

_Institute of Human Virology, Abuja, Nigeria; Plateau State Human Virology Research Centre, Jos, Nigeria; National Health Research Ethics Committee, Abuja, Nigeria; National Agency for Food and Drug Administration and Control, Abuja, Nigeria; National Agency for the Control of AIDS, Abuja, Nigeria; University of Ottawa and The Ottawa Hospital, Ottawa, Ontario, Canada; Institute of Human Virology, University of Maryland School of Medicine, Baltimore, Maryland, USA_

**Background:** There is a paucity of high-level clinical trials in Nigeria for several reasons, which include the limited number of trained investigators, inadequate training and mentorship in the implementation of clinical trials to international standards, inadequate investment in the training of national coordinating, ethical and regulatory agencies leading to poor supervisory functions, and stigmatization and sensitivities from past suboptimal clinical trials. Therefore, there is a need to build the capacity of these national coordinating agencies, the research team, the research laboratory and the community in preparation for future HIV vaccine clinical trials.

**Method:** Funding from the Canadian Global Health Research Initiative (i.e., the Canadian HIV Vaccine Initiative, CHVI; the Canadian Institutes of Health Research, CIHR; the International Development Research Centre, IDRC; and the Canadian International Development Agency, CIDA) created an excellent opportunity to develop in-country capacity for HIV vaccine clinical trials according to the national HIV vaccine plan.

**Results:** During this period, eight trainees from NACA, NHREC, NAFDAC and the research team completed training on statistical methods and epidemiology at the Institute of Human Virology in Nigeria (IHVN), which has reinforced their understanding of the scientific basis of the ongoing sero-discordant study. Three trainees attended an introductory course on clinical trials at IHVN and 12 trainees attended a site base research ethics workshop supervised by NHREC and successfully attained a certificate in good clinical laboratory practice (Table O-24-1). Courses taught included international ethical guidelines for biomedical research involving human subjects, research ethics regulation in Nigeria (i.e., highlights of the national code for health research ethics), ethical issues in clinical trials, the informed consent process, research misconduct, etc. These have strengthened the ethical values of the research team as well as those of the officers of

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**Table O-24-1: Training of officers from national coordinating, ethical and regulatory bodies**

<table>
<thead>
<tr>
<th>Training</th>
<th>Trainees</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statistical methods and epidemiology</td>
<td>8 people from NACA, NAFDAC, NHREC and the research team</td>
<td></td>
</tr>
<tr>
<td>Research ethics training</td>
<td>12 people from NHREC and the research team</td>
<td>All compliant with good clinical laboratory practice</td>
</tr>
<tr>
<td>Introductory course on clinical trials</td>
<td>5 people from the research team</td>
<td></td>
</tr>
<tr>
<td>Regulation and monitoring of clinical trials</td>
<td>3 people from NAFDAC and IHVN</td>
<td>2 people were denied visas</td>
</tr>
</tbody>
</table>

IHVN = Institute of Human Virology in Nigeria, NACA = National Agency for the Control of AIDS, NAFDAC = National Agency for Food and Drug Administration Control, NHREC = National Health Research Ethics Committee.
these coordinating agencies. Additional training and mentoring of these officers and the research team in clinical trials and vaccine-related oversight is ongoing at the University of Maryland in Baltimore and at the University of Ottawa. Consequently, three officers from the NAFDAC and IHVN attended 2 weeks of clinical research training at the University of Ottawa/Ottawa Hospital on systematic reviews, the responsible conduct of research, budgeting, data management, etc. These trained officers now oversee the ongoing sero-discordant couple cohort study (i.e., mock trial) in preparation for future HIV vaccine trials with a higher level of commitment and teamwork. As a result, the partnership between these officers and the research team has been strengthened. Thus, the research team participated in the modification of the recently launched national HIV vaccine plan for 2012 organized by these national coordinating officers and has subsequently been included in critical stakeholder meetings organized by these agencies.

**Conclusion:** Our study has shown that early interaction and integration through contractual agreements, meetings, site base visits, training and mentorship of national coordinating bodies is critical for building in-country capacity for successful clinical trials as this creates commitment, promotes ownership and heightens participation and oversight by trained government officials. These efforts have led to the successful development of the ongoing vaccine preparedness cohort of sero-discordant couples by the trained research team monitored by trained regulatory and ethical officers.

**Limitations:** The Canadian embassy’s refusal to issue temporary visas for some officers of the national coordinating agencies to attend scheduled training sessions led to the sessions being rescheduled. This highlights the need for early involvement of Canadian and Nigerian government officials in such collaborations. Security challenges in Jos (the main study site) prolonged the enrollment process and delayed site base visits and training. As a result, satellite sites with fewer security issues were initiated (i.e., the Dalhatu Araf Specialist Hospital and Federal Medical Centre, Keffi).

See online Appendix O-24 for PowerPoint presentation.

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**O-25 Capacity development and strengthening in preparation for HIV vaccine trials in Tanzania and Burkina Faso: work packages and key results from the Burkina Faso site**

Isidore Traore, Nicolas Meda, Philippe Mayaud, Mariam Noelie Hema, Nicolas Nagot, Djeneba Drabo

Centre de Recherche Internationale pour la Santé, Université de Ouagadougou, Ouagadougou, Burkina Faso

**Background:** The HIVTAB project (HIV vaccine trials in Tanzania and Burkina Faso) was funded by the European and Developing Countries Clinical Trials Partnership (EDCTP) in Tanzania and partly by the French National Agency for AIDS Research (ANRS) in Burkina Faso to strengthen research capacity in preparation for future HIV vaccine trials. Here, we describe the work packages in Burkina Faso and some key results.

**Methods:** The study protocol has been approved by both Burkina Faso’s national ethics committee and the institutional review board of the London School of Hygiene and Tropical Medicine. We had performed a situation analysis of sexual and reproductive health and HIV needs in Ouagadougou. In Ouagadougou, from September 2009 to September 2011, high-risk young women <25 years of age were screened and enrolled for 24-month follow-up. Sociodemographic, clinical and biological data were collected to describe HIV/STD and pregnancy prevalence and incidence. Immunological testing (by enzyme-linked immunosorbent spot assay [ELISPOT]) was performed. A community advisory board was established. Training in good clinical practice and data management and courses at the master’s and doctoral level were delivered to the research team and community members.

**Results:** The geomapping of sex work venues was enumerated: there were 1,088 professional female sex workers (FSWs) in 125 sex work locations (median 10 women/site) and 2,487 bar waitresses in 699 bars (median 3 women/site). Young FSWs were screened and 333 enrolled. Professional FSWs constituted 28% (92/333) of our sample. Participants’ median age was 21 years (interquartile range [IQR] 19–23). HIV prevalence at screening was 9% (55/638); the median number of total sexual partners (clients and regular partners) was 3 (IQR 2–5). The mean percentage of condom use with clients at enrollment was 95%. The follow-up rate was 83% (1544 follow-up visits done among 1846 scheduled). Pregnancy incidence was 23/100 person-years (p-y). We recorded zero HIV seroconversions (0/403 p-y, 95% confidence interval 0–0.009). Community members and all staff were trained in research ethics. A total of 3 distance learning courses, 2 at the master’s level and 1 at the doctoral level, were offered to young researchers. Plasma separation (peripheral blood mononuclear
cells) processing and ELISPOT technology were transferred from Montpellier (France) to the Bobo-Dioulasso site.

**Conclusion:** With this low HIV incidence and after the capacity-building activities, the Ouagadougou cohort should be suitable for the early phases of HIV vaccine trials (phases I/II).

Note: No PowerPoint presentation is available for abstract O-25.

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**O-26 Ensuring good clinical laboratory practice (GCLP) compliance during the conduct of HIV-1 vaccine clinical trials at Kenya AIDS Vaccine Initiative (KAVI)**

Bashir Farah, Simon Ogola, Jackton Indangasi, Omu Anzala

Kenya AIDS Vaccine Initiative (KAVI), Nairobi, Kenya

**Background:** The Kenya AIDS Vaccine Initiative (KAVI) is currently conducting a Phase I HIV-1 vaccine trial. The implementation of good clinical laboratory practice (GCLP) and pursuit of accreditation in clinical trial laboratories are essential. GCLP provides guidelines to ensure that clinical trial laboratories work to standards that ensure the reliability, quality and integrity of the work and results generated.

**Objective:** To implement and conduct HIV-1 vaccine trials in accordance with GCLP guidelines.

**Methods:** KAVI, in collaboration with the International AIDS Vaccine Initiative, has developed guidelines and checklists to facilitate the implementation of GCLP, and laboratory staff is trained on the basic concepts. The quality system includes a comprehensive audit program ensuring compliance: (a) an annual external audit, in pursuit of accreditation, by Qualogy, UK, an independent accrediting body associated with the British Association of Research Quality Assurance; (b) six monthly audits of safety labs and GCLP compliance by the Clinical Support Laboratory, Johannesburg; and (c) monthly internal audits by site staff. Following the audits a report is issued detailing the findings and recommendations. In response the laboratory has implemented corrective actions to address the findings.

**Results:** The laboratory was granted conditional GCLP accreditation on 3rd February 2006 and full accreditation was granted by Qualogy from November 2006 up to 2012.

**Conclusion:** The implementation of GCLP standards in a laboratory is a slow process but has innumerable advantages. Improved quality systems, results, greater efficiency and teamwork are the key benefits. Accreditation constitutes formal recognition of the laboratory’s competence.

See online Appendix O-26 for PowerPoint presentation.
Biomedical and clinical sciences

P-1 Acting locally: innate mucosal immunity in resistance to HIV infection in Kenyan commercial sex workers


McMaster Immunology Research Centre, Michael G. DeGroote Institute for Infectious Disease Research, Department of Pathology and Molecular Medicine, McMaster University, Hamilton, Ontario, Canada; Department of Medical Microbiology, University of Manitoba and Public Health Agency of Canada, Winnipeg, Manitoba, Canada; University of British Columbia, BC Centre for Disease Control, Vancouver, British Columbia, Canada; Department of Medical Microbiology, University of Nairobi, Nairobi, Kenya

Background: Cohort studies of commercial sex workers (CSWs) in Nairobi were among the first to identify a subgroup of women who were highly exposed to HIV-1 for many years but remained uninfected. Although resistance to infection may correlate with genetic, viral, immunological and/or sociobehavioral factors, the precise mechanism(s) of resistance in these women continue(s) to be an active area of investigation. Since natural resistance is usually mediated by innate immune mechanisms, we focused on determining whether expression and function of innate signaling pathways were altered locally in the genital mucosa of HIV-resistant (HIV-R) CSWs. Pattern recognition receptors (PRRs) play a central role in initiating innate immune activation and inflammation. To date, a number of PRR families have been identified in humans, including Toll-like receptors (TLRs), retinoic acid-inducible gene 1 (RIG-1)-like receptors and NOD-like receptors. Increasing evidence supports the hypothesis that immune activation has a critical role in HIV-1 infection and chronic disease progression. In a previous study, we showed that chronic untreated HIV-1 infection was significantly associated with increased TLR expression and responsiveness of peripheral blood cells, which may perpetuate innate immune activation and dysfunction. In contrast, studies of HIV-R CSWs have shown generally lower levels of basal gene transcription and downregulation of proinflammatory cytokines in T helper cells, suggesting an “immune quiescent” state.

Methods: Study participants were members of the Pumwani cohort of CSWs in Nairobi, Kenya. Written informed consent was obtained from all study participants. The study was approved by ethics review boards from the University of Manitoba and Kenyatta National Hospital. Cervical mononuclear cells (CMCs), cervical epithelial cells (CECs) and cervicovaginal lavage (CVL) from cohorts of HIV-R, HIV-positive (HIV-P) and HIV-susceptible (HIV-S) CSWs were investigated. Quantitative reverse transcription polymerase chain reaction was used to measure expression of innate signaling molecules. Stimulation of CMCs and response to pathogen-associated molecular patterns were conducted in vitro. Cytokines and chemokines were measured using enzyme-linked immunosorbent assays.

Results: Our results demonstrated that selected PRRs, including TLR2, RIG-I, Mda-5 and UNC93B, were significantly reduced in expression in CMCs from HIV-R compared to HIV-S and HIV-P groups. TLR4, TLR6, TLR8, IFN-γ and JAK2, as well as indoleamine-2,3-dioxygenase 1, were also significantly decreased in HIV-R. Both TLR7 and TLR8 showed reduced expression in CMCs of HIV-R compared to HIV-S and HIV-P in separate assessments from 3 years. Although baseline levels of secreted TNF-α and IL-10 were reduced in CMCs of HIV-R, these cytokines were highly stimulated following exposure to ssRNA40 in vitro. Similarly, CECs from HIV-R also expressed reduced levels of TLR2, TLR4, RIG-I, Mda-5 and UNC93B, but importantly, expression of TLR3 and TLR7 was remarkably enhanced in these cells. NF-κB and AP-1 were highly expressed and activated in CECs from HIV-R, while expression of ISG15 was markedly reduced. Lastly, inflammatory cytokines IL-1β, IL-8 and RANTES were detected at lower levels in CVL of HIV-R.

Conclusions: Overall, although reduced expression of numerous PRRs in CECs and CMCs may reflect an innate quiescent state with lower immune activation/inflammation, CECs expressed high levels of endosome-associated TLRs poised to rapidly
respond to HIV-1 and CMCs were highly responsive when stimulated with viral ssRNA. Thus, a finely controlled balance of basal immune quiescence with a focused, potent innate anti-viral knockout response probably plays a critical role in local resistance to sexual transmission of HIV-1. It still remains to be determined how expression of PRRs is differentially regulated in the mucosa of HIV-R. For example, it must be determined whether these alterations are genetic or sustained by exposure to HIV-1 through sex work. Further understanding of the precise mechanisms of local innate signaling in the genital mucosa may provide clues for the development of novel prophylactic strategies to protect against sexual transmission of HIV and inform HIV vaccine development.

The median (142738 pg/mL) of IP-10 in active TB/HIV-negative participants and in active TB/HIV-co-infected participants were higher than the median (94.24 pg/mL) of IP-10 in the controls, although the difference was not statistically significant.

**Conclusion:** Interleukin 2, IL-17, and IL-1ra had diagnostic potential as they could differentiate between the participants who were infected with *M. tuberculosis* and the controls. Interleukin 2 and IL-1ra were most promising as they were expressed in high levels with antigen stimulation and were low in the un-stimulated samples. Interleukin 17 can be used as a biomarker of *M. tuberculosis* infection both in HIV-infected and HIV-uninfected individuals. Further studies are needed to explore the potential IL-2, IL-1ra and IL-17 individually and in combination in diagnosis of *M. tuberculosis* infection.

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**P-2 In vitro profiling of Mycobacterium tuberculosis antigen induced cytokine production among patients with active tuberculosis**

Julius Oyugi, Zipora Machuki, Blake Ball, Omu Anzala

**University of Nairobi, Nairobi, Kenya**

**Introduction:** Early diagnosis of tuberculosis (TB) is important in the control of TB both for treatment and prevention of transmission of the disease to others in the community. The conventional methods have limitations in terms of speed, specificity and sensitivity. Furthermore, the sensitivity of most TB diagnostic methods is lower in severely immunocompromised persons. Therefore, in countries like Kenya, where the prevalence of HIV is higher than 5% in the general population, there is a need to identify a biomarker that can be used to accurately diagnose *Mycobacteria tuberculosis* infection.

**Methodology:** This was a cross-sectional study where 69 participants were recruited. Blood was collected into nil (unstimulated), antigen (ESAT-6 and CFP10 stimulated) and mitogen (positive control) tubes and incubated at 37°C for 16–24 h. The plasma was harvested and used for QuantiFERON–TB Gold (QFT) enzyme-linked immunosorbent assay (ELISA) and cytokine analysis.

Luminex multiplex cytokine assay was performed to determine the levels of 17 cytokines/chemokines. The antigen-dependent cytokine/chemokine production was determined by subtracting the concentration in the nil tube from that in the antigen tube.

**Results:** There were 62 (75.6%) pulmonary TB participants and 7 (8.54%) controls. Interleukin 2, IFN-γ and IL-1ra were produced in significantly high amounts in antigen stimulated whole blood from *M. tuberculosis*-infected participants compared to controls who were QFT negative and HIV negative. Interleukin 17 was consistently produced in significantly lower amount in participants with active TB regardless of their HIV status compared to controls.

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**P-3 Dynamic range of Nef functions in chronic HIV-1 infection**

Philip Mwimanzi, Tristan Markle, Zabrina Brumme, Takamasa Ueno

**Simon Fraser University, Burnaby, British Columbia, Canada**

HIV-1 Nef is a multifunctional protein required for efficient viral replication and pathogenesis. However, detailed assessment of the dynamic functional range of in vivo derived Nef sequences, and their relevance to HIV-1 disease progression, has yet to be performed. Here, we assessed the dynamic ranges, functional co-dependence and clinical correlates of five of Nef’s major functions (CD4 and HLA-1 down-regulation, CD47 up-regulation, and enhancement of viral infectivity and viral replication in peripheral blood mononuclear cells) in a panel of 46 clonal sequences from chronically HIV-1-infected individuals. Overall, patient-derived Nefs possessed no expression or stability defects and were generally highly functional relative to the control strain SF2. Nef-mediated infectivity, replication and CD47 up-regulation exhibited broad dynamic functional ranges while those of HLA-1 and CD4 down-regulation were comparably narrower. Eighty per cent of patient-derived Nefs were active for at least three of the functions examined. Functional co-dependencies were identified, including positive correlations of CD4 down-regulation with infectivity, replication and CD47 up-regulation, and between CD47 up-regulation and replication. Results support strong selection pressure to maintain Nef’s various functions even during relatively advanced infection. The identification of Nef-mediated viral infectivity as an inverse correlate of CD4+ T-cell count highlights this specific function as particularly relevant to HIV-1 pathogenesis.

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P-4 ABO, Duffy and secretor phenotype profiles among voluntary blood donors in Nairobi, Kenya

Nadia Chanzu, Walter Mwanda, Julius Oyugi, Omu Anzala

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Background: Blood group antigens are expressed on red blood cells; however, these antigens can also be expressed on some other cells, particularly the surface of epithelial cells, and may be found in mucosal secretions. The gene known to determine the secretion of these blood group antigens is the secretor gene known as the secretor fucosyltransferase 2 (FUT2) gene. In many human populations 80% secrete ABO antigens (termed secretors) while 20% do not (termed non-secretors). Furthermore, there are disease conditions that are associated with secretor status. It is against this background that this study is proposed.

Hypothesis: There are distinct correlations between erythrocyte blood group antigen expression profiles and mucosal blood group antigen secretor status in the Kenyan population.

Objectives: The objectives of this study were to determine ABO and Duffy blood group antigen phenotype profiles among voluntary non-remunerated blood donors in Nairobi, Kenya, and to determine blood group antigen secretor/non-secretor phenotype profiles among voluntary non-remunerated blood donors in Nairobi, Kenya.

Methodology: This study enlisted 142 voluntary adult blood donors of both genders (106 male and 36 female) from the Nairobi Regional Blood Transfusion Centre. The donors were aged 18 to 50 years. The laboratory analyses were carried out at the Kenya AIDS Vaccine Initiative (KAVI) laboratories, Nairobi. Blood typing was determined using standard serological techniques using monoclonal and polyclonal antibodies to the ABO and Duffy blood group antigens respectively. Secretor phenotyping was determined using anti-H Lectin (Ulex europaeus) to the salivary H antigen. This was performed to determine the variable expression of the H blood group antigen in saliva: secretor and non-secretor phenotypes. Specimens were collected from each study participant once informed written consent had been obtained. The Kenyatta National Hospital/University of Nairobi Ethical and Research Committee approved the study.

Results: Frequency profiles of the ABO phenotype demonstrate blood group O as the most common, and AB the least common, with 95% of the blood donors as Rhesus positive. Furthermore, this study demonstrates a high prevalence of the Duffy-negative phenotype among the donors. Secretor phenotyping results show 85% of the donors were secretors and 15% non-secretors. Blood group O secretors were the majority in comparison to non-O blood group secretors. With regards to the Rhesus-positive individuals 84% were secretors and 16% were non-secretors, while in Rhesus-negative individuals, all were secretors. Interestingly, there were no Rhesus-negative non-secretor study cases.

Conclusion: This is the first report to document the secretor phenotype frequency among a Kenyan population. We postulate further investigations will demonstrate the correlations between secretor status and the HIV infectious process. A better understanding of the mucosal mechanism of protection associated with blood group antigen expression profiles may provide additional insight into the development of new HIV preventive technologies.

P-5 Sexual and reproductive health in HIV-positive young women in an urban clinic in Uganda: causes of vaginal discharge

Christine Katusiime, Andrew Kambugu, Walter Schlech, Rosalind Parkes-Ratanshi

Prevention Care and Treatment Department and Research Department, Infectious Diseases Institute, College of Health Sciences, Makerere University, Kampala, Uganda; Department of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada; Canada–Africa Prevention Trials (CAPT) Network

Introduction: The presence of abnormal genital discharge can indicate underlying vaginal/cervical infections. An abnormal genital discharge in HIV-positive persons may also be indicative of sexually transmitted infections and can lead to increased transmission of HIV to partners as well as affecting pregnancy outcomes. In resource-limited settings, treatment is usually based on a syndromic approach: patients presenting with a genital discharge are treated with a combination of drugs that target the most frequent etiological agents. Usually there is little attempt in resource-limited settings to make a precise microbiological diagnosis.

Study objective: We performed this study to determine the etiology of abnormal genital discharge among HIV-positive young people attending an urban clinic in Kampala, Uganda, who presented with an abnormal genital discharge.

Study design: The Infectious Diseases Institute provides prevention, care and treatment services to a population of 10,000 HIV-positive persons. The young adult HIV clinic hosts a population of over 820 HIV-infected young adults. Young people aged 15-24 years attending the HIV clinic at the Infectious Diseases Institute from April 2011 to May 2012 who reported abnormal genital discharge were included in this study. High vaginal and cervical or urethral swabs were obtained from all participants during a sterile vaginal speculum examination. These samples were sent for microscopy and culture.
investigation into causes of abnormal vaginal/urethral discharge in this population is important, as often the condition is treated by syndromic management in resource-limited settings, but the causes are still not well defined and untreated STIs in HIV-positive individuals may increase HIV transmission rates and adversely affect fertility and pregnancy outcomes. This work was possible because of integrated sexual reproductive health (SRH) services in our young adult HIV clinic. In our opinion, integration of SRH services with HIV care is essential in controlling STIs in this critical population.

Fig. P-5-1: Culture findings for patients with abnormal vaginal discharge. Data presented as percent of patients. Culture results for 31 patients were not available at time of compiling data.

Table P-5-1: Symptoms, microscopy and culture findings in cases with abnormal vaginal discharge

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Discharge</th>
<th>Itch</th>
<th>Ulcers/sores</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>71</td>
<td>38</td>
<td>25</td>
<td>134/112*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Microscopy</th>
<th>Yeast cells</th>
<th>Pus cells</th>
<th>T. vaginalis</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40</td>
<td>21</td>
<td>3</td>
<td>64/81†</td>
</tr>
</tbody>
</table>

T. vaginalis = Trichomonas vaginalis.

*Some patients had more than 1 symptom concurrently.
†Microscopy results for 31 cases were not available at the time the data were compiled for this report.

Results: A total of 195 HIV-positive young people accessed treatment from the newly established young adult HIV/STI program during this period. Of these, 112 young women (57.4%) presented with an abnormal genital discharge (Table P-5-1). The median age and CD4+ counts of those with an abnormal discharge were 22 years (interquartile range [IQR]: 20–23) and 397 cells/µL (IQR: 197–572) respectively. Thirty-two (28.6%) had WHO HIV stage III and IV disease and 54.1% had CD4+ counts < 350 cells/µL. Thirty-eight participants (33.9%) had no significant bacterial growth on culture and were treated as having pelvic inflammatory disease with syndromic management, a combination of ciprofloxacin, metronidazole and doxycycline. Of those with a positive culture, 59 (52.7%) had Candida albicans, 3 (2.7%) had Klebsiella pneumoniae, 3 (2.7%) had Streptococcus pyogenes, 3 (2.7%) had Neisseria gonorrhoeae and 3 (2.7%) had Staphylococcus aureus (Fig. P-5-1). Only three participants (2.7%) had positive isolates of Trichomonas vaginalis (Fig. P-5-1).

Conclusions: The predominant isolate in HIV-positive young adults with symptomatic genital discharge was C. albicans. Gonorrhea and T. vaginalis infection were the primary STIs identified. Unfortunately, chlamydia nucleic acid amplification testing was not available due to resource contraints in our setting. Further

P-6 Sexual and reproductive health in young people with HIV in an urban clinic in Uganda: the important role of syphilis

Christine Katusiime, Andrew Kambugu, Walter Schlech, Rosalind Parkes-Ratanshi

Prevention Care and Treatment Department and Research Department, Infectious Diseases Institute, College of Health Sciences, Makerere University, Kampala, Uganda; Department of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada; Canada–Africa Prevention Trials (CAPT) Network

Introduction: Bacterial sexually transmitted infections (STIs) such as syphilis exact a heavy toll in terms of morbidity and mortality in the developing world; thus, diagnosis and treatment of curable STIs in HIV-infected persons can aid in preventing spread to partners. Syphilis in HIV-positive people may increase HIV transmissibility and adversely affect reproductive health. There are limited data on syphilis/HIV co-infection in adolescents and young adults in developing countries. Our newly established young adult HIV/STI program introduced regular serological screening for syphilis in 2011 to detect and treat infected patients.

Study objective: This study aimed to test all HIV-infected young adults for syphilis between April 2011 and April 2012 who presented to the sexual reproductive health team in our HIV clinic with symptoms suggestive of genital ulcer disease, urethral discharge or an abnormal vaginal discharge.

Study design: The Infectious Diseases Institute provides prevention, care and treatment services to a population of 10,000 HIV-positive persons. The young adult HIV clinic hosts a population of over 820 HIV-infected young adults, which is about 8% of the total clinic population. From April 2011 to April 2012, the young adult clinic provided care to 3,360 HIV-positive young people. Following the establishment of the adolescent/young adult HIV/STI program in April 2011, 173 HIV-infected young adults aged 15–24 years who presented with symptoms of genital ulceration, urethral discharge or an abnormal vaginal discharge between April 2011 and April 2012 were treated. All of these were serologically screened for syphilis using a Treponema
**Introduction:** In Uganda about 1.6 million pregnancies occur yearly. An increasing proportion of these births, about 104,000, are to HIV-positive women. Ugandan national guidelines recommend that HIV-positive pregnant women be given antiretroviral drugs for prevention of mother-to-child transmission (PMTCT) from 14 weeks' gestation. At birth, the mothers continue with antiretroviral therapy (ART), and the children also receive ART. Despite this PMTCT intervention, some children still become infected. We wished to ascertain if drug resistance contributed to failures of PMTCT identified in the Medical Research Council – Uganda Virus Research Institute (MRC/UVRI) lab.

**Methods:** The MRC/UVRI lab tested infants from HIV-positive mothers for infection 6 weeks after birth. DNA was extracted from infant whole blood and HIV infection detected by proviral DNA polymerase chain reaction (PCR). HIV drug resistance sequencing was carried out from the infant proviral DNA and with condylomata acuminata and an additional 4 participants (17.4%) were diagnosed with genital herpes (Fig. P-6-2). Only 1 participant (4.3%) was HIV/syphilis/hepatitis B co-infected (Fig. P-6-2).

**Conclusion:** Thirteen percent of HIV-positive young adults with symptomatic STIs had positive syphilis serology in our urban HIV clinic. We were unable to fully screen the entire adolescent HIV clinic population due to limited resources. Females presented more for sexual reproductive health (SRH) services, so they were tested more frequently. Screening for syphilis in HIV-positive adolescents and young adults is an effective initiative for detecting and controlling a treatable STI in this cohort and has important implications for reproductive health and HIV transmission. Ideally, all HIV clinic patients should have comprehensive STI screening by dedicated SRH teams in HIV clinics.

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**Table P-6-1: Comparison of baseline values for HIV-positive participants**

<table>
<thead>
<tr>
<th>Study group</th>
<th>Co-infected with syphilis (n = 23)</th>
<th>Not co-infected with syphilis (n = 150)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females</td>
<td>22 (95.6)</td>
<td>140 (93.3)</td>
<td>0.67</td>
</tr>
<tr>
<td>Participants on antiretroviral therapy</td>
<td>5 (21.7)</td>
<td>26 (17.3)</td>
<td>0.61</td>
</tr>
</tbody>
</table>
from maternal plasma derived RNA. Drug resistance mutations were identified using the Stanford HIV drug resistance database.

**Results:** Of the 95 children tested in the MRC/UVRI lab, five were found to be HIV positive by DNA PCR. DNA sequencing and analysis indicated one transmitted virus had the M184V resistance mutation. A sample from the mother of this infant near the time of birth also had the M184V mutation. Seven of the eight copies/mL (based on a 1:10 dilution of baby plasma).

**Discussion and conclusion:** For the most part, HIV transmission from mothers to their babies was not due to drug resistance. However, there was clear transmission of the resistant M184V virus from one mother to her baby. Before becoming pregnant this mother had been on highly active ART but had a history of poor adherence; however, she reported good adherence all through her pregnancy. While this is only one case, this report highlights the risk of poor ART adherence, especially the risk of transmission of a drug-resistant virus, for those who are pregnant. In this case, despite the resistance mutation, first-line drugs are still working.

### Table P-8-1: Incidence of anemia in the study subjects

<table>
<thead>
<tr>
<th>Duration of treatment</th>
<th>No. of new cases</th>
<th>No. of subjects</th>
<th>Annual incidence</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 weeks</td>
<td>7</td>
<td>61</td>
<td>7/(61 x 5/52) = 1.19</td>
<td>0.03–0.19</td>
</tr>
<tr>
<td>13 weeks</td>
<td>18</td>
<td>61</td>
<td>18/(61 x 13/52) = 1.18</td>
<td>0.18–0.40</td>
</tr>
</tbody>
</table>

CI = confidence interval.

### Table P-8-2: Comparison of patients’ risk factors for anemia and neutropenia

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Baseline</th>
<th>OR (95% CI)</th>
<th>p value</th>
<th>After 13 weeks</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anemia</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>5 (25%)</td>
<td>0.49 [0.16–1.56]</td>
<td>0.223</td>
<td>10 (50%)</td>
<td>1.08 [0.38–3.03]</td>
<td>0.884</td>
</tr>
<tr>
<td>Female</td>
<td>21 (42.4%)</td>
<td></td>
<td></td>
<td>25 (48.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 count &lt; 250</td>
<td>20 (50%)</td>
<td>4.33 [1.47–12.8]</td>
<td>0.006</td>
<td>2 (100%)</td>
<td></td>
<td>0.146</td>
</tr>
<tr>
<td>CD4 count ≥ 250</td>
<td>6 (18.8%)</td>
<td></td>
<td></td>
<td>33 (47.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-trimoxazole</td>
<td>14 (36.8%)</td>
<td>1.06 [0.39–2.85]</td>
<td>0.907</td>
<td>23 (60.5%)</td>
<td>3.22 [1.19–8.71]</td>
<td>0.019</td>
</tr>
<tr>
<td><strong>Neutropenia</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (50%)</td>
<td>1.74 [0.61–4.93]</td>
<td>0.297</td>
<td>14 (70%)</td>
<td>2.52 [0.84–7.57]</td>
<td>0.094</td>
</tr>
<tr>
<td>Female</td>
<td>19 (36.5%)</td>
<td></td>
<td></td>
<td>25 (48.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 count &lt; 250</td>
<td>17 (42.5%)</td>
<td>1.23 [0.47–3.19]</td>
<td>0.667</td>
<td>1 (50%)</td>
<td>0.86 [0.05–14.3]</td>
<td>0.919</td>
</tr>
<tr>
<td>CD4 count ≥ 250</td>
<td>12 (37.5%)</td>
<td></td>
<td></td>
<td>37 (55.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-trimoxazole</td>
<td>17 (44.7%)</td>
<td>1.7 [0.63–4.56]</td>
<td>0.291</td>
<td>23 (60.5%)</td>
<td>1.86 [0.71–4.86]</td>
<td>0.203</td>
</tr>
</tbody>
</table>

CI = confidence interval; OR = odds ratio.
the study. All the patients were on co-trimoxazole 960 mg daily for prophylaxis. Patients had complete blood counts and CD4/CD8 cell counts at baseline and at six weeks after initiation of treatment.

Results: Prevalence of anemia was 34.5% (n = 72) (cut-off hemoglobin for males < 13.0 g/dL and females < 12.0 g/dL) and that of neutropenia was 35.9% (n = 72) (cut-off < 1500 cells/μL). Anemia incidence rates of 1.19 per person year in HIV/AIDS patients after 5 weeks of zidovudine combination regimen treatment and 1.18 per person year after 13 weeks were observed (Table P-8-1). The incidence rates of anemia and of neutropenia at 6 weeks were 1.2 per person year and 4.6 per person year, respectively. Anemia was generally associated with a CD4 count of < 250 (odds ratio [OR] = 5.0) while neutropenia was not (OR = 1.1). Co-trimoxazole prophylaxis was a risk factor for anemia (OR = 3.2, p = 0.019) (Table P-8-2) but not for neutropenia (OR = 1.06, p = 0.997). Female patients were 1.44 times more likely to develop anemia than male patients within the study group.

Discussion: The analysis of the impact of highly active anti-retroviral therapy on hematological abnormalities in this study also has limitations. Since our study was relatively small and of limited duration, we cannot exclude the possibility that with a larger study or with a longer follow-up period a significant clinical benefit could be associated with improvements in hematological parameters in comparison with a control arm of patients not on treatment, and it would also be unethical to deny patients treatment.

Conclusion: Anemia and neutropenia occur early in patients on antiretroviral treatment regimens containing zidovudine. Our study indicates that co-trimoxazole is a risk factor of anemia. More studies are required to establish this finding.

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P-10 Functional characteristics of effector and recall natural killer (NK) cellular responses and their comparison with adaptive T cell responses in HIV-vaccinated subjects and risk populations

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Le Dantec University Hospital, Dakar, Senegal

Background: The development of an effective HIV-1 vaccine represents one of the major challenges in biomedical research. The failure to attain an effective T-cell-based vaccine against HIV highlights the urgent need for investigation of other cellular immune correlates against HIV protection especially in clinical trial settings and in risk cohort populations. Unlike CD4+ and CD8+ T-cell responses, less attention has been given to the role of innate natural killer (NK) responses in protection against HIV. Indeed, the existence of recall NK responses in HIV-infected patients and the role of NK cells in resistance to infection have been shown in some studies. In this project, we aim to investigate recall NK responses in HIV-infected adults and uninfected infants who have received HIV-vaccine candidates in West Africa and compare them with responses in HIV-exposed but uninfected adults and with HIV-specific memory CD4+ and CD8+ T-cell responses.

Methodology design: We will recruit 24 healthy Gambian infants from the Medical Research Council Sukuta birth cohort...
who received a single dose of the MVA.HIVA candidate HIV-1 vaccine in 2010 when they were 5 months old, and 24 healthy controls who received placebo. We will also re-consent 19 HIV-infected adults from Guinea-Bissau who were vaccinated with a CAFO cationic liposome adjuvanted HIV-1A immunogen and 6 controls in a European and Developing Countries Clinical Trials Partnership trial in 2009. We will also recruit 60 individuals from the HIV-discordant couple cohort in Dakar, Senegal, and 20 commercial sex workers from the Dakar cohort. Peripheral blood mononuclear cells from these samples will be incubated with whole HIV-1 clade A peptide pools of Gag, Env and Reg peptides for 18 h and then analysed for NK and T-cell functional responses, which will characterize activation, regulatory and memory phenotypes.

**Expected results:** From this study, we expect to demonstrate the existence of recall NK responses in HIV-vaccinated subjects as well as in exposed subjects and establish NK functional responses as measurements of HIV protective outcomes in vaccine trials.

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**P-12 Evolution of neutralizing antibodies in acute heterosexually acquired HIV-1C infection in Botswana**

Keabetswe Bedi, Sununguko Wata Mpoloka, Joseph Mahkema, Takafira Mduluza, Simani Gaseitsiwe, Vladimir Novitsky, Rosemary Musonda, Max Essex

University of Botswana, Gaborone, Botswana

**Background:** Thirty years after the discovery of HIV, there is still no potent and efficacious vaccine against the infection. The recent discovery of potent and broad neutralizing antibodies against HIV-1 has revived interest in better understanding the role of neutralizing antibodies in the prevention of HIV transmission.

**Methods:** A cohort of eight HIV-1C acutely infected individuals were enrolled and followed for a period of 12 to 48 months. Plasma samples were collected prospectively during the follow-up period. Viral RNA was extracted from plasma collected at approximately week one post enrolment and used as a template for cDNA synthesis, amplification of HIV-1C gp160, cloning into pcDNA3.1/D/V5-His expression vector, and co-transfection of 293T cells to generate single round infectious pseudovirus particles. A standardised neutralization assay based on TZM-bl cells was used to determine the autologous neutralizing capacity.

**Results:** Five pseudoviruses were generated for three individuals, four pseudoviruses for two, two pseudoviruses for two, and one pseudovirus for one individual. Autologous neutralizing antibodies appeared between four weeks and nine months post seroconversion for seven out of eight individuals. One individual’s autologous neutralizing antibodies were not detected until 42 months post seroconversion. In general, viruses displayed varying intra-subject as well as inter-subject neutralization sensitivities. The potency of the neutralization increased over time for all subjects except one, who had very potent autologous neutralization that coincided with transient viral load decline. This potency, which was first observed at five months, was significantly higher at this time point than at a later time (33 months).

**Conclusions:** HIV-1C neutralizing antibodies toward the transmitted virus develop around five months after seroconversion and
reach significant potency by two years of infection. Neutralizing antibody development lags behind, as evidenced by the consistent lack of neutralizing capacity of the contemporaneous plasma.

P-13 The immune correlates of HIV susceptibility in the foreskin of men from Rakai, Uganda

Jessica L. Prodger, Ronald Gray, Godfrey Kigozi, Fred Nalugoda, Ronald Galiwango, Taha Hirbod, Maria Wawer, Nelson Sewankambo, David Serwadda, Rupert Kaul

University of Toronto, Toronto, Ontario, Canada; Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA; Rakai Health Sciences Program, Kalisizo, Uganda; Karolinska Institutet, Stockholm, Sweden; Makerere University, Kampala, Uganda

Background: Trials of medical male circumcision (MMC) for HIV prevention demonstrated the foreskin is a main site of HIV acquisition in heterosexual men. However, there is significant heterogeneity in individual susceptibility to HIV infection. We hypothesized that differences in susceptibility to HIV might be related to the abundance and/or function of T cell subsets within the foreskin.

Methods: Participants were recruited from men in the Rakai Community Cohort Study (RCCS) who opted to undergo elective MMC. Sexual behavior and partner data were available through the RCCS; STI testing was performed on the man and his female partner at the time of circumcision. We identified men who (1) were HSV-2 positive (known to increase HIV susceptibility) or (2) were regularly exposed to HIV but remained seronegative (HESN men). Novel techniques were established to isolate foreskin T cells, and ex vivo stimulation followed by intracellular staining was used to examine (i) CD4+ T cell co-expression of CCR5; (ii) Th17 and Treg cells; (iii) CD8 T cell TNF-α and IFN-γ production; and (iv) HIV-specific T cell responses. There was rigorous blinding of lab personnel performing all immune assays.

Results: Ninety HIV-negative men were enrolled: 38 were found to be HSV-2 positive by serology and 21 reported regular unprotected sex with an HIV-infected partner (HESN men). Asymptomatic HSV-2 was found to be associated with an increased frequency of CCR5+ CD4 T cells in the foreskin (36% vs. 46%, p = 0.01). In HESN men we found a decrease in the frequency of Th17 cells (6.4% vs. 9.7%, p = 0.007), a highly HIV-susceptible T cell population, and also decreased CD8 T cell TNF-α production (33.3% vs. 44.8%, p = 0.004).

Conclusions: We have found that a state of increased HIV susceptibility (HSV-2 infection) is associated with increased CCR5 expression on foreskin CD4 T cells, while the foreskins of HESN men have reduced Th17 cells and reduced production of the pro-inflammatory cytokine TNF-α. This suggests that a foreskin immune milieu with low CCR5 expression, low Th17 levels, and low levels of pro-inflammatory cytokines may be one that is resistant to HIV infection.

P-13-A Consistent patterns of Gag-mediated HIV replication capacity over the course of the North American epidemic (1979–present)

Laura Cotton, Denis Chopera, Kali Penney, Jonathan Carlson, Eric Martin, Anh Le, Tallie Kuang, Bruce Walker, Jonathan Fuchs, Susan Buchbinder, Theresa Wagner, Mina John, Simon Mallal, Beryl Koblin, Kenneth Mayer, Art Poon, Mark Brockman, Zabrina Brumme

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Background: The extent to which HIV replication capacity (RC) has changed over the epidemic’s course and the influence of HLA-associated immune pressure as its driving force remain unknown. We performed a comparative study of immune escape and RC in historic (1979–1989) and modern Gag subtype B sequences from North America.

Methods: Using phylogenetically informed methods, we identified HLA-associated Gag polymorphisms in a historic cohort (n = 239; 1979–1989). We also generated recombinant NL4-3 viruses encoding clonal plasma HIV-1 RNA Gag from 108 historic and 58 modern (2002–2008) sequences. Viral RC was measured using a GFP reporter T-cell assay and results were normalized to NL4-3 controls.

Results: Ninety-five percent of HLA-associated polymorphisms identified in the historic cohort were consistent with published modern escape pathways. Overall, the prevalence of HLA-associated polymorphisms in the general population increased a median 1.3-fold between historic and modern sequences; however, in many cases this was influenced by differences in HLA allele frequencies between the HIV-infected populations examined. Of note, the prevalence of the B*27-associated R264K escape mutation increased from 0.4% to 1.3% in the general population over time despite the B*27 allele frequency remaining constant at 2.5%. No significant difference in viral RC was observed for Gag recombinant viruses constructed from historic (1979–1989) sequences (median 0.97, inter-quartile range [IQR] 0.85–1.04, n = 108) compared to modern (2002–2008) sequences (median 0.96, IQR 0.83–0.110, n = 58) (p = 0.6683). However, in both historic and modern cohorts, host expression of HLA-B*27
was associated with modestly lower RC ($p = 0.007$). Gag codons associated with lower RC, including $567A$, were identified in an exploratory analysis.

**Conclusion:** Gag-mediated viral RC appears to have remained relatively consistent since the beginning of the North American epidemic. Additionally, there is limited evidence for HLA-driven viral sequence evolution during this time. These results do not support rapid and substantial accumulation of HLA-driven escape mutations in circulating North American HIV-1 sequences and indicate that CTL immune responses targeted towards conserved regions within Gag will continued to provide protection against the most commonly circulating strains of HIV-1 in North America.

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**Behavioural science and epidemiology**

**P-14 “We want to have control of our lives”: stories of young women participating in an HIV prevention intervention**

Ditiro Laetsang, Anne Cockcroft, Grace Wanjiru Waichigo, Nobantu Marokoane, Neil Andersson

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**Background:** Young women are at particularly high risk of HIV infection in Southern Africa, related to gender violence and transactional and transgenerational sex. As part of an HIV prevention cluster randomized controlled trial in Namibia, Botswana, and Swaziland, we implemented a structural intervention among young women aged 18–24 years. The Focused Workshop (FW) aimed to reduce the effects of choice disability (the inability to implement protective choices) among young women by training them in personal development and business skills and supporting them to start small enterprises. The FW included an initial workshop covering self-esteem, peer pressure, negotiation skills, and teamwork, and it supported participants to start small enterprises and to access existing support programmes for small businesses. We undertook a process evaluation of this intervention using the most significant change technique.

**Methods:** Project field coordinators collected stories from 76 young women participants, across the 38 FW intervention sites in the three countries, describing the “the most significant change” to their lives that they attributed to their involvement in the FW intervention. The facilitators took notes of the stories as they were told and checked their accuracy with the interviewees. The field teams then met to review the stories and chose those that best illustrated expected and unexpected effects of the intervention in each country. We carried out a thematic analysis of all the collected stories and report here on the preliminary findings from this analysis.

**Findings:** Many young women told stories about personal change, whether or not they had been successful in their small enterprises. A prominent theme was about feeling more in control of their lives, more able to take their own decisions, and more independent: “I can better my life.” “I gained courage and became brave to start something to make my life better … I really see the difference in my life. FW gave me hope and change in my life in a positive way. I dream big every day and want to change the lives of others” [28-year-old woman in Swaziland].

Some women specifically mentioned taking decisions to protect themselves: “I am empowered to take decisions that I know will be best for me. I will not put myself at risk because of a man. If I don't want, it means I don't want. He can respect that or he must get lost. I am empowered with information to better my life; no one can take that away from me” [25-year-old woman in Namibia].

Many described how they now valued themselves more, and saw themselves as “someone special.” They talked of having dreams, plans, and hope for the future: “I dream big every day.” “I now know that, instead of depending on someone to take care of me, I can get help to open my business. … Me and my child we will never go hungry … I know I am not useless like my grandmother used to tell me. I know I have value and can be someone in life” [25-year-old woman in Namibia].

The young women felt able to persevere to reach their goals. Some explained how they had gone back to school or been able to get a job.

Some described how others now viewed them differently because they were able to make a contribution, for example to family finances, or because they were seen to be working seriously towards their goals: “Now I see myself as a person among other people. At home they also recognize that I am helping out. I think I can now be able to stand on my own, be independent” [26-year-old woman in Swaziland]. “I have created a name for myself in the village and people now know me for good things. People continue to show me support, they ask me how far it is going and what I have managed. It has been a good change in my life. I am going places I never knew existed” [26-year-old woman in Botswana].

**Conclusion:** The FW participants described changes beyond being able to make an income. The “self-capitalisation” aspect of
the intervention and the way it increased feelings of self-worth and fostered independence might be important. The FW intervention may mediate personal changes that help young women to protect themselves against HIV infection.

P-15 Great expectations: women’s experiences of pregnancy while HIV positive and on antiretroviral therapy in Uganda

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Simon Fraser University, Vancouver, British Columbia, Canada; Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA; Centre for Global Health, Massachusetts General Hospital, Boston, Massachusetts, USA; Mbarara University of Science and Technology, Mbarara, Uganda

Evidence that women of reproductive age in Uganda carry a double health burden of being the most disproportionately affected group of the HIV pandemic and face pressures to have many children suggests that greater insight into the realm of combining reproductive health (RH) and HIV is needed. As access to antiretroviral treatment (ART) and prevention efforts is becoming increasingly common, much has been written on individual reasons that influence pregnancy among HIV-positive women using ART. Less has been written about socio-cultural and politico-economic factors beyond the individual that also end up playing a role in shaping pregnancies. Understanding different aspects that influence pregnancy among HIV-positive women on ART is important for programs working to incorporate a more comprehensive reproductive health approach within current HIV prevention efforts. This paper is based on 5 months of fieldwork in Mbarara, Uganda, in 2011 and builds on interviews with HIV-positive women about their desires to have children. The paper grounds multi-level forces in an ethnographic foundation that allows the static view of pregnancy desires to encompass a more dynamic, comprehensive understanding by building off of social and cultural norms and shifting political and economic forces. This paper works to understand a structural reality where women must adapt and accommodate to different levels of influence and power in environments they may only partially control. Careful interpretation of how pregnancy desires are shaped and sometimes constrained by not only individual intentions but also multi-level influences is important when designing prevention programs that focus on the needed integration of HIV and RH services. Under this approach, those who may exhibit greater influence on pregnancy outcomes than the woman herself can also be targeted for future education and prevention programs.

P-16 Enhancing adherence to antiretrovirals (ARVs) through intensified health education and adherence counseling—a case study of Baba Dogo Health Centre, Nairobi

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University of Nairobi/University of Manitoba Collaborative Group, Nairobi, Kenya

Background: Many studies have been carried out on adherence to antiretroviral (ARV) drugs. However, due to the dynamism of adherence it is important to study it in different settings. Non-adherence to ARVs poses serious public health challenges including viral mutation leading to treatment failure and high risk of transmission.

Methods: HIV+ clients were enrolled into a comprehensive care centre. At baseline, health education was offered and blood samples were taken for CD4 counts. Those who met ARV initiation criteria as per Kenyan guidelines were taken through a phase of intensified health education and counseling on ART adherence using standardized tools. The intensified health education/counseling was done in a combination of 5 components including adherence I (an intense session of HIV awareness and confirmation of client’s CD4+ cell results), adherence II (a preparation for ARV initiation), and adherence III (a follow-up session 1 month after ARV initiation addressing drug side effects). An additional education/counseling session was undertaken any time a client’s adherence was below 95%. Monthly support groups were also held and community health workers engaged to strengthen adherence at home. Adherence was monitored through pill recall and pill counts for 3 days. Pill refills were given for 2 weeks at first, then monthly, and clients could graduate to 2 or 3 months’ supply depending on adherence. Data for the previous 3 visits were analyzed for this study.

Results: A total of 583 clients (males: 187 [32%]; females: 396 [68%]) were taken through the intensified health education and adherence counseling and their data analyzed. Median age was 34 years. A total of 538 clients (92%) had adherence of greater than 95% while only 44 (8%) had adherence less than 95%.

Conclusion: Intense health education/adherence counseling is instrumental in enhancing adherence. Empowerment of clients on ART through health education/counseling should be emphasized in our settings.
**P-17 Factors associated with disclosure of status to family in people living with HIV**

**Lawrence Mbuagbaw, Lehana Thabane**

McMaster University, Dundas, Ontario, Canada

**Background:** People living with HIV (PLHIV) require considerable amounts of family and social support. This becomes difficult when they have not disclosed their status to their family members or partners. Disclosure of status is an important component of care in PLHIV that sometimes affects their ability to seek social support, obtain medical care and adhere to medication. Stigma and discrimination are often the main reasons why PLHIV do not disclose their status. The World Health Organization and Joint United Nations Programme on HIV/AIDS recommend “beneficial disclosure” such that the ethical perspectives are considered for both the infected and uninfected. Such disclosure should be voluntary. In order to develop strategies to improve “beneficial disclosure,” it is important to investigate the characteristics of people who disclose their HIV status voluntarily.

**Objectives:** The objective of this cross-sectional analysis was to investigate the factors associated with disclosure of status in the Cameroon Mobile Phone SMS (CAMPS) baseline data set.

**Methods:** The CAMPS data set consists of 200 PLHIV receiving care from the Yaoundé Central Hospital in Cameroon. Cameroon is a resource-limited country in central Africa, with an HIV prevalence of 5.3%. The CAMPS trial was the first mobile phone technology trial in Cameroon, comparing the use of motivational text messaging versus usual care to improve adherence to antiretroviral therapy (ART). This trial ran from December 2010 to June 2011. The Yaoundé Central Hospital is the pioneer centre for ART research in Cameroon and caters to more than 6000 clients. We used standard multivariable binary logistic regression techniques to build models predicting disclosure of status dichotomized as disclosed or not disclosed. The independent variables were age, gender, level of education (primary or less and secondary or higher), stage of disease (presence or absence of an AIDS-defining condition), regimen (first line or second line), duration on ART (months) and the use of reminder methods.

**Results:** One hundred and ninety-four participants had data on disclosure of status. The majority had disclosed their status

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**Table P-17-1: Baseline characteristics of participants in the CAMPS trial**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Status disclosed</th>
<th>Status not disclosed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 180)</td>
<td>(n = 14)</td>
</tr>
<tr>
<td><strong>Age, years, mean (SD)</strong>*</td>
<td>40.5 (10.11)</td>
<td>32.1 (7.04)</td>
</tr>
<tr>
<td><strong>Gender, (n) (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>132 (68.0)</td>
<td>12 (6.2)</td>
</tr>
<tr>
<td>Male</td>
<td>48 (27.4)</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td><strong>Level of education, (n) (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None or primary</td>
<td>71 (36.6)</td>
<td>4 (2.1)</td>
</tr>
<tr>
<td>Secondary or university</td>
<td>109 (56.2)</td>
<td>10 (5.2)</td>
</tr>
<tr>
<td><strong>Opportunistic infection, (n) (%)</strong>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>57 (29.7)</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>No</td>
<td>121 (63.0)</td>
<td>12 (6.3)</td>
</tr>
<tr>
<td><strong>AIDS-defining illness by CDC classification,† (n) (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>134 (71.7)</td>
<td>8 (4.3)</td>
</tr>
<tr>
<td>No</td>
<td>39 (20.9)</td>
<td>6 (3.2)</td>
</tr>
<tr>
<td><strong>Regimen, (n) (%)‡</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First line</td>
<td>160 (83.8)</td>
<td>13 (6.8)</td>
</tr>
<tr>
<td>Second line</td>
<td>17 (8.9)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td><strong>Duration on ART, months, median (Q1, Q3)§</strong></td>
<td>28.0 (9.09, 47.2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>33.5 (17.75, 53.75)</td>
<td></td>
</tr>
<tr>
<td><strong>Adherence, visual analogue scale, mean (SD)§</strong></td>
<td>90.5 (12.93)</td>
<td>91.9 (9.02)</td>
</tr>
<tr>
<td><strong>Reminder methods, (n) (%)¶</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>44 (23.8)</td>
<td>5 (2.7)</td>
</tr>
<tr>
<td>One</td>
<td>114 (61.6)</td>
<td>7 (3.8)</td>
</tr>
<tr>
<td>Multiple</td>
<td>15 (8.1)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

**ART** = antiretroviral therapy; **CDC** = Centers for Disease Control and Prevention; **SD** = standard deviation.

*Two missing.
†CDC classification: A3, B3, C1, C2, C3 (3). Seven missing.
‡Three missing.
§Ten missing.
¶Nine missing. The reminder methods reported were personal verbal reminders by individuals, phone alarms, meal times, timing with TV shows and watches.

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**Fig. P-17-1:** Forest plot of multivariable regression analysis showing factors associated with disclosure of status. **ART** = antiretroviral therapy, **CI** = confidence interval, **OR** = odds ratio.
Younger people were less likely to have disclosed their status.

FGDs were carried out with adolescents aged 1–18 years. FGDs were carried out with adolescents aged 18–19 years from Kanya Motsha Adolescent Centre (KMAC) in Soweto, South Africa, to facilitate dialogue around the language of sex, relationships, peer pressure, and HIV prevention messaging. Girls discussed the looming threat of community as well as sexual violence and how sexual decision-making was sometimes based on avoiding sexual assault. The shortsightedness and perceived inaccessibility of their future goals and aspirations meant that girls sometimes transacted sex for gifts, money, transportation, and food. Boys spoke about the importance of reporting back to male friends about having sex with many girls. Boys also discussed the need for immediate gratification and the lack of importance placed on future goals. Such goals seemed unrealistic and unattainable in their socio-economic and cultural contexts. Boys and girls spoke about navigating peer and sexual relationships without having an adult or trusted role model to talk to.

Discussion: The participants who had not disclosed their status were, on average, about eight years younger than those who had. It is possible that the pressures from stigma and discrimination weigh more on younger people as they try to assert themselves in society.

Conclusion: These findings re-emphasize the need for disaggregation of data by age and the urgency of developing specific interventions for younger people. Creating facilitative environments for younger people to disclose their status to their families and entourage may be an important way to prevent the spread of HIV and encourage better integration in societies where stigma is rife. Measures should also be taken to limit the harms of disclosure.

P-18 Putting adolescent health on the map—body mapping as a youth-driven research methodology in Soweto

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Body mapping falls under an umbrella of psychosocial tools known as memory work. Body mapping uses art to communicate significant life milestones, important future goals, the physical and emotional tolls of illness, the importance of support systems, and personal expressions of hope and courage.

Understanding adolescent sexual health language: Using an adapted methodology, we used body mapping as a research tool with adolescents. While the technique remained the same, exercises were revised to understand how adolescents negotiated HIV risk and sexuality in the context of a hyper-endemic HIV setting. The adapted methodology used new exercises based on three focus group discussions (FGDs) held in December 2011. FGDs were carried out with adolescents aged 18–19 years from Kanya Motsha Adolescent Centre (KMAC) in Soweto, South Africa, to facilitate dialogue around the language of sex, relationships, peer pressure, and HIV prevention messaging. Girls discussed the looming threat of community as well as sexual violence and how sexual decision-making was sometimes based on avoiding sexual assault. The shortsightedness and perceived inaccessibility of their future goals and aspirations meant that girls sometimes transacted sex for gifts, money, transportation, and food. Boys spoke about the importance of reporting back to male friends about having sex with many girls. Boys also discussed the need for immediate gratification and the lack of importance placed on future goals. Such goals seemed unrealistic and unattainable in their socio-economic and cultural contexts. Boys and girls spoke about navigating peer and sexual relationships without having an adult or trusted role model to talk to.

Piloting a new research tool: In July 2012 two body mapping workshops were held in Soweto where adolescents were guided through exercises based on information gathered in the FGDs. Participants began with a life-sized tracing of their physical body, and their work evolved to include a second body figure (support shadow). Participants used symbols and images to tell stories of where they came from (acknowledging the significance of the past), physical and emotional experiences of illness and loss, the meaning behind their support systems (using the support shadow), discussions of life’s challenges and obstacles, and personal expressions of hope and courage in a time of HIV/AIDS. There were ongoing discussions of symbols, images, and color. For each body mapping exercise, the trained facilitator suggested locations on the 4 × 6 foot piece of paper for the symbols participants developed. For example, symbols/images that suggest where the artist has come from are drawn in the bottom left corner of the map. Those representing life goals are placed in the top right corner and the challenges and obstacles that may hinder the fulfillment of the goals fill the space in between. The purpose behind the suggested space was to offer direction to the artists and to keep them from filling the entire paper before all 18 exercises were completed. Soweto body mapping participants could communicate using English or one of two South African languages, isiZulu or isiXhosa. A research assistant was present during workshops for translation purposes. In addition, a KMAC counselor was available in the event that difficult emotions or challenging situations arose. It was particularly important to have a counselor present at the end of each day, when the adolescents were given the opportunity to come together as a group to discuss any of the images they had drawn that day or to comment on the daily proceedings and the overall experience. These discussions, in English, isiZulu, or isiXhosa, were recorded and transcribed.

Results: Data revealed an embodied meaning of adolescent HIV vulnerability. The pilot workshops suggested that adolescents required immediate, structured follow-up support sessions to assist with issues that arose as a result of their artistic explorations, personal expressions, and realities. Responding to this need for follow-up support sessions, the trained counselor who was available to the adolescents during the body mapping workshops incorporated monthly sessions at KMAC where
participants gathered to discuss topics such as career planning, discovering one’s personal strengths, HIV risk, and problem-solving techniques pertaining to negative peer pressure and unhealthy relationships.

Conclusions: Body mapping is a safe and supportive outlet for what otherwise remains as “unspeakable” and encourages youth to tell stories about censored topics related to sexual risk. Body mapping takes more time and funding than traditional interviews and FGDs alone. However, the technique facilitates getting at the censored issues, which other research methodologies may not be best suited to capture, due to their dependence on words.

P-19 Alcohol use counseling among HIV positives attending a semi-rural HIV care setting, Uganda: a missed opportunity

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Introduction: Alcohol impacts the HIV epidemic via increased risk for sexual transmission of HIV and decreased adherence to antiretroviral therapy (ART) and may lead to more rapid HIV disease progression. Sub-Saharan Africa (SSA) has the highest prevalence of HIV infection and heavy episodic drinking in the world. Uganda in SSA has an HIV prevalence rate of 7.3% and high alcohol consumption among those who drink. Few interventions to decrease alcohol consumption and alcohol-related sexual risk behaviors have been developed or implemented in SSA. It is not known whether and how alcohol consumption reduction counseling is occurring in HIV clinical care.

Methods: This is a mixed methods study, comprised of a prospective cohort study of HIV-positive alcohol consumers (past year) entering HIV care, as well as qualitative observations of patient/counselor staff interactions at the Immune Suppression Syndrome (ISS) Clinic in Mbarara, southwestern Uganda.

Results: To date, 53 patients have been enrolled in the prospective cohort. Thirty-eight per cent are female, the median age is 29 years (interquartile range [IQR]: 23–36 years), the median CD4 cell count is 329 cells/mm³ (IQR: 214–448), and 77% reported consuming alcohol in the 3 months prior to baseline. One third (3%) of participants reported at baseline that they were asked about alcohol consumption during a visit at the ISS Clinic in the prior 3 months, while 6% reported discussing the need to decrease alcohol consumption at a clinic visit. Thirty-eight (38) clinic observations revealed that alcohol use was discussed during most individual and group counseling sessions. However, the discussions were not detailed and not all patients were asked about alcohol use. It appears that clinic staff may refrain from discussing alcohol use with patients from religious affiliations that prohibit alcohol use and/or pregnant women.

Conclusions: Our findings suggest that although alcohol has an important impact on HIV care, it is not systematically discussed by ISS Clinic workers. Culturally relevant strategies to help HIV positives decrease their alcohol consumption are needed, and clinic visits with guided health education talks and individual client counseling may provide such opportunities.

P-20 Preparing for new biomedical HIV prevention technology implementation in South Africa

Kate Snyder, Melissa Wallace, Benjamin Brown, Peter Newman

Background: Biomedical HIV prevention trials have begun to demonstrate the potential to prevent HIV infection in HIV-negative populations across the world. Results from a range of global trials assessing efficacy of vaccines, microbicides, and antiretroviral-based pre-exposure prophylaxis (PrEP) have reported varying levels of partial efficacy for reducing HIV risk, particularly in high-risk populations such as heterosexual women and men who have sex with men (MSM). However, other multi-site trials such as VOICE (MTN003) and FEM-PrEP reported inconclusive results or were terminated early, likely due partly to low adherence, issues that underscore the importance of acceptability analysis. Each of these new prevention technologies will require different methods of use and delivery among both generalized and key populations, all with unique preferences for use. Due to the partial efficacy of these strategies, they will also need to be promoted within a combination “prevention package” of other risk-reduction methods such as consistent condom use, and careful messaging will be required to convey important concepts including that of partial efficacy. This study explores how diverse populations in South Africa, including MSM, adolescents, and heterosexual women, will want to access and utilize a biomedical “prevention package” and how these products and services should be promoted to meet these needs.

Study aims and objectives: This 2½-year study aims to inform strategy prioritization and healthcare planning through the following objectives: (1) to investigate and compare target user group (heterosexual adult, MSM, and adolescent) acceptability of vaccine, microbicide, and PrEP products; (2) to evaluate user group acceptability of possible delivery systems for these products; (3) to assess user group understanding of the “partial efficacy” concept using abstract questioning and scenarios; and (4) to gather context-specific marketing expertise from country
leaders around the promotion of these products in general and key populations.

**Methods:** The study is structured in three phases. In Phase I a pilot investigation will collect preliminary data on objectives 1, 2, and 3 through 8 purposively selected focus groups with heterosexual adults, MSM, and adolescents; in Phase II the full quantitative investigation will survey 1,000 respondents from the target groups on objectives 1, 2, and 3; in Phase III, the implementation phase, 10 in-depth interviews will be conducted with market and consumer experts, in order to explore ways in which these new technologies might be promoted to target populations. The study will be conducted at the Desmond Tutu HIV Foundation in Cape Town, South Africa.

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**P-21 Barriers and facilitators to adherence in user-dependent trials**

Julie Ambia, Kawango Agot, Joyce Olenja, Omu Anzala

University of Nairobi, Nairobi, Kenya; Impact Research and Development Organization, Kisumu, Kenya

**Introduction:** To date, no single adherence intervention for oral pre-exposure prophylaxis (PrEP) and microbicides has been shown to be effective as they have only been tested in clinical trials and not evaluated. Hence, in most cases, trial investigators in consultation with the host community implement several adherence interventions, hoping they will be effective. Suboptimal adherence to investigational products has been associated with ineffectual outcomes in previous randomized controlled trials on vaginal diaphragms, vaginal microbicides and PrEP. Instances have been documented where non-eligible women manipulated their responses to facilitate enrollment during the screening visits. During the early phases of a trial involving 1% tenofovir (a microbicide), 135/398 women had simultaneously enrolled in two HIV trials, contrary to the inclusion criteria; apart from the financial incentive, other reasons for co-enrollment included a perceived low risk of discovery and peer pressure. These women were also aware that trial staff had no way of knowing whether they used the study product or not, and they chose not to use any study products for safety reasons. Of note is that conducting HIV trials is time and resource intensive, so there should be a focus on maximizing the return on the investment by ensuring high adherence by participants. However, that is not usually the case as discussed above. Further, due to futility, the FEM-PrEP trial was stopped prematurely as a result of suboptimal adherence. It can be argued that it does not make sense to spend substantial financial resources on trial after trial only to discover that people did not take the drug as instructed, leading to an ineffectual trial outcome. Adherence to study procedures is the most significant determinant of the safety and efficacy of HIV trials. Adherence is a complex behaviour influenced by several determinants, which include the individuals participating in the study, their family members, their friends, their communities, and their perceptions about health and illness, as well as the study staff. Several facilitators of and barriers to adherence have been identified across trials and in different geographical locations. These facilitators and barriers vary from place to place as well as from context to context. It is necessary to examine the facilitators and barriers within the Kenyan context in order to identify which ones are relevant and which ones are not and to identify ways to minimize the barriers in future trials. To date, there are no comprehensive studies that have been carried out to determine the risk factors of suboptimal adherence in phase II and III HIV prevention trials in Kenya. It is for this reason that a study to determine predictors of suboptimal adherence among trial participants in the FEM-PrEP and Partners PrEP studies is proposed. Data will be collected from former trial participants in the FEM-PrEP study, where poor adherence (<40%) led to ineffectual outcomes, and the Partners PrEP study, where high adherence (82%) demonstrated PrEP’s protective effect against HIV.

**Methods:** This study will have a cross-sectional design, using a mixed method approach that combines both quantitative and qualitative methods. The data collection process comprises a quantitative survey (n = 433), 16 focus group discussions (FGDs), and 36 in-depth interviews (IDIs). The quantitative survey primarily intends to describe factors participants identify as influencing adherence. For the descriptive analysis, frequencies, percentages, means, and standard deviations will be computed. Logistic regressions will be used to identify predictors of low adherence levels. The IDIs and FGDs intend to answer the “why” and “how” questions on factors influencing adherence arising from the quantitative survey.

**Expected outcomes:** Understanding the factors that promote or hinder adherence will provide meaningful input into assessing the likelihood of adherence in potential participants and customizing adherence strategies and messages to suit the different needs of participants.

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**P-22 A phone call promotes prevention of HIV/AIDS**

Maureen Akolo, Francis Nyamiobo, Joshua Kimani, Larry Gelmon

Kenya AIDS Control Project, Nairobi, Kenya

**Background:** HIV/AIDS is a pandemic condition that has proved to be a burden in sub-Saharan Africa. Prevention messages and services are being used to cut down the incidence rate. In September 2008 the University of Manitoba/University of Nairobi
Collaborative Group in Nairobi, Kenya, stepped up prevention amongst discordant couples in order to increase the uptake of prevention services by improving attendance in support groups.

Methodology: A longitudinal study on all HIV-positive patients in the Pumwani Maternal and Child Health Clinic aged 12 years and older and reportedly sexually active was done for two years. They were counseled on status disclosure, safer sex practices and partner testing. The ones whose partners tested HIV negative were enrolled into a discordant couples support group while the discordant couples joined the general HIV support group. Both support groups received a monthly phone message a week prior to the meeting and met once a month. The discordant couples were divided into groups of 5 couples and the couples in turn sent messages to each couple in their group; hence, each couple received 5 messages reminding them of meetings.

Results: A total of 238 discordant couples were enrolled. The attendance at the discordant support group went up to 85% from 63% while the attendance at the general support group went up from 60% to 67%. The number of discordant couples attending the support group together rose from 35% to 73%. Seventy per cent of the index patients reported having a much happier marriage, up from 45%. There was an increase in correct and consistent condom use from 50% to 90% among discordant couples. Most couples reported having fewer stigmas and felt that somebody cared.

Conclusion: Involvement of people affected by or infected with HIV/AIDS in prevention activities is promoting a higher percentage of HIV prevention amongst discordant couples.

P-23 Sex work and vertical healthcare programming in South Africa: access to healthcare in tension

Jenny Coetzee, Brett Bowman, Janan Dietrich

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Introduction: HIV is the leading cause of death and the primary contributor to the quadruple burden of disease in South Africa. Given its significant social and economic effects, the country’s health department has prioritised its prevention and management through considerable investments in various screening protocols, psycho-educational programmes and access to healthcare in the form of state-sponsored treatments. Although marketed to the country as a whole, these services and treatments are often strategically targeted at those considered to be most at risk for the transmission of HIV. Although sex work is a crime in South Africa, sex workers nonetheless form an important subset of this target population and so it is unsurprising that a preponderance of sexual health research on sex workers has emphasised the HIV risk implied by this vulnerable group. In tracking the recent and unprecedented increase in international support towards improving healthcare in developing countries, the HIV – sex worker nexus has received a large proportion of funding towards disease-specific or vertical healthcare programmes (VHP). The perceived impact of such programming has not been thoroughly explored.

Aim: As part of a broader qualitative project, which explored the barriers and facilitators to sexual and reproductive healthcare (SRHC) for female street- and hotel-based sex workers in a major South African city centre, this paper describes and explores the perceived impact of VHP on the lives of sex workers.

Method: Participants were recruited via a snowballing strategy facilitated by a local non-governmental organisation committed to securing equitable sex worker rights through advocacy. In-depth semi-structured interviews were conducted with 11 female street-based sex workers. These interviews were guided by a modified World Health Organization data collection instrument. Data were transcribed verbatim and analyzed using guidelines for thematic analysis.

Findings: VHP of certain HIV/STI or prenatal services was not perceived to be always successful. The participants perceived the major obstacles to effective VHP to be largely logistical, ideological and psychological. Logistical obstacles reported included having to wait for significantly long periods in extremely long queues, as well as miscommunications between healthcare facilities. Ideologically, staunch religion-driven persecution and punitive moral judgments leveled at the sex workers by the healthcare workers (HCW) within the VHPs meant that the participants were reluctant to make use of such facilities. Lastly, the perceived prejudice and stigmatisation of the participants by HCW was reported to be psychologically injurious such that the sex workers relayed an aversion to health-seeking behaviour even in dire circumstances. The participants perceived the combination of these obstacles as reducing them to vectors of disease rather than human beings. This “vectorisation” of the participants was exacerbated by the fact that as sex workers they were treated differently from the “normal” population. The SRHC needs of the participants were almost always reduced to HIV prevention and management and this made accessing other health system offerings as women very challenging. Providing VHP to the seemingly unique needs of sex workers was thus paradoxically perceived to undermine rights-based efforts to provide equitable healthcare access to the participants as women more broadly.

Conclusions: The disease-specific nature of VHP appears to have alienated sex workers from the public SRHC systems designed to serve them. Designing programmes to serve those populations identified to be “at risk” may in fact reduce the end users...
P-24 Long-term healthcare interruptions and attrition among HIV+ patients in Uganda
Edward J. Mills, Steve Kanters, Mary Odit, Daniel Mwehire, Jean Nachega, Barbara Mukasa
University of Ottawa, Ottawa, Ontario, Canada

Background: Retaining patients in clinical care is necessary to optimize antiretroviral treatment (ART). Some patients will discontinue from care for periods of time and then either re-enter care or be lost to follow-up. We aimed to examine the extent of healthcare interruptions and attrition within a cohort receiving ART in Uganda.

Methods: Using a large cohort from a hospital-based organization providing universal ART and HIV clinical care, we assessed the characteristics and risk factors for the primary outcomes of healthcare interruptions, defined as a 12-month absence from care, and loss to follow-up, defined as absence from care for more than 12 months without re-engagement in care. We included patients aged 14 years and above. We assessed these outcomes over time using Kaplan–Meier analysis and multivariable regression.

Results: Of 6970 eligible patients, 784 (11.2%) had a healthcare interruption of at least 12 months and 217 (3.1%) were lost to follow-up. Patients experiencing healthcare interruptions had higher baseline CD4 T-cell counts at ART initiation, defined as >250 cells/mm$^3$ (odds ratio [OR]: 1.29, 95% confidence interval [CI]: 1.11–1.50), and lower levels of education less (OR: 0.76, 95% CI: 0.62–0.92). Adolescents were much more likely to be lost to follow-up (odds ratio [OR]: 3.11, 95% CI: 2.23–4.34). In contrast, having a partner (OR: 0.22, 95% CI: 0.16–0.31) or being sexually active at baseline (OR: 0.40, 95% CI: 0.28–0.55) were protective.

Conclusions: Within this cohort, long periods of unsupervised healthcare interruptions were common. Efforts to ensure regular attendance of patients are necessary to maximize the benefits of ART and clinical care.

P-25 Increased mortality among HIV-positive men on treatment: survival differences between sexes explained by late initiation in Uganda
Steve Kanters, Eric Druyts, Daniel Mwehire, Barbara Mukasa, Mary Odit, Edward J. Mills
Simon Fraser University, Burnaby, British Columbia, Canada

Background: We assessed the relationship between gender and survival among adult patients newly enrolling on antiretroviral therapy (ART) in Uganda and the potential role of mediating factors in favoring women’s access to HIV care.

Methods: From an observational cohort study, we assessed survival and used logistic regression and differences in means to compare men and women who did not access care through antenatal services. A mediational analysis that considered gender as the initial variable, time to death as the outcome, initial CD4 count as the mediator and age as a covariate was performed using an accelerated failure time model with a Weibull distribution.

Results: Between 2004 and 2011, a total of 4775 patients initiated ART, and after exclusions 4537 (93.2%) were included in analysis. Men were more likely to initiate ART with a WHO disease stage III or IV (odds ratio [OR]: 1.46, 95% confidence interval [CI]: 1.29–1.66) and with more advanced immunosuppression (median baseline CD4 124 cells/mm$^3$, interquartile range [IQR]: 43–205 versus 147 cells/mm$^3$, IQR: 68–212, p < 0.0001) compared to women. Men were at an increased risk of death compared to women (hazard ratio: 1.38, 95% CI: 1.03–1.83). Baseline CD4 cell counts account for 43% of the increased risk of death in men (95% CI: 22–113%). Access to care via antenatal services did not explain differences in outcomes.

Conclusions: In this cohort there is a marked increase in risk of mortality for men, and approximately half of it can be attributed to their poorer engagement in care.
**P-26 High HIV-1 prevalence and willingness to participate in HIV vaccine trials in a population-based study among fishing communities around Lake Victoria, Uganda**


Makerere University College of Health Sciences, Entebbe, Uganda

**Background:** HIV epidemics in sub-Saharan Africa are generalized, but high-risk subgroups exist within these epidemics. A recent study among fisherfolk communities (FFC) in Uganda showed high HIV prevalence and incidence. However, those findings may not reflect population-wide HIV rates in FFC since the study population was selected for high-risk behaviour.

**Methods:** We conducted a community-based cohort study to determine the population representative HIV rates and willingness to participate in future vaccine trials (WTP) among FFC, Uganda. Following a community-wide census in 8 fishing communities (2 lakeshores and 6 islands), a random sample of 2200 participants aged 18–49 years was selected. Data were collected on HIV risk behaviours and WTP, and venous blood was collected for HIV testing using rapid HIV tests with enzyme immunoassay confirmation. Adjusted prevalence proportion ratios (adj.PPRs) of HIV prevalence were determined using log-binomial regression models.

**Results:** Overall HIV prevalence was 26.7%, and it was higher in females than males (32.6% vs. 20.8%, p < 0.0001). Prevalence was lower among fishermen (22.4%) than housewives (32.1%), farmers (33.1%), and bar/lodge/restaurant workers (37.0%). The adj.PPR of HIV was higher among females than males (adj.PPR = 1.50, 95% confidence interval [CI]: 1.20–1.87) and participants aged 30–39 years (adj.PPR = 1.40, 95% CI: 1.10–1.79) and 40–49 years (adj.PRR = 1.41, 95% CI: 1.04–1.92) compared with those aged 18–24 years. Other factors associated with HIV prevalence were low education, previous marriage, polygamous marriage, alcohol use before sex and use of marijuana. Willingness to participate in hypothetical vaccine trials was 89.3% and was higher in males than females (91.2% vs. 87.3%, p = 0.004) and among island communities compared with lakeshore ones (90.4% vs. 85.8%, p = 0.004).

**Conclusion:** The HIV prevalence in the general fisherfolk population in Uganda is similar to that observed in the “high-risk” fisherfolk. FFC have very high levels of WTP in future HIV vaccine trials.

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**Structural and operational issues**

**P-27 East African Canada–Africa Prevention Trials (CAPT) Network collaboration**

Juliet Mpendo, Winnie Muyindike, Emily Nyanzi, Joshua Kimani, Pontiano Kaleebu, Andrew Kambugu, Josephine Birungi

Uganda Virus Research Institute – International AIDS Vaccine Initiative (UVRI–IAVI) HIV Vaccine Program, Entebbe, Uganda

**Background:** The East African Canada–Africa Prevention Trials (CAPT) Network collaboration came about as a result of the CAPT Network initiative formed in 2006 establishing a research consortium comprising institutions in three countries in Africa and Canada coordinated through three research “hubs,” located in East Africa, South Africa and Canada. The idea was to promote research between African and Canadian researchers by strengthening research capacity; training and overall coordination of research activities.

**Methods:** The East African hub has its secretariat at the Uganda Virus Research Institute (UVRI) in Entebbe. It coordinates the activities of five sites: The AIDS Support Organization (TASO), the Infectious Diseases Institute, Mbarara University of Science & Technology, the University of Nairobi and UVRI, which is also a partner. It provides administrative and research support to the sites by strengthening the sites’ infrastructural capacity to conduct research and by building capacity through training and coordination of face-to-face meetings, teleconferences and annual meetings where research ideas are identified and shared. As a site, UVRI has been involved in cohort development, technology transfer, social sciences studies, immunological studies, inter-site networking and project management.

**Results:** The East African hub recruited a project manager to coordinate CAPT activities. It spearheaded memoranda of understanding with the various sites, ensured implementation of site work plans and transferred funds to the sites. Capacity building through various training sessions has taken place at various sites. Through inter-site networking, a discordant couple cohort has been developed. The hub has coordinated two CAPT annual meetings in Uganda and coordinated travel and logistics for site staff to attend the 2011 CAPT annual conference in Pietermaritzburg. At the UVRI, a high-risk cohort in fishing communities has been established. A qualitative study on male circumcision was conducted in this cohort and there are ongoing epidemiological studies. Samples from individuals who suffered from yellow fever in northern Uganda are being collected for immunological studies.
Conclusion: We have observed that through the East African CAPT Network, sharing of experience and capacity is mutually beneficial and supports African scientists to conduct relevant research in their countries in support of the global HIV prevention effort.

P-28 HIV prevention through a small grants initiative: INSTANT (Initiative for Strengthening HIV/AIDS Training and Networking)
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Regional AIDS Training Network, Nairobi, Kenya

The program: Through INSTANT, the Initiative for Strengthening HIV/AIDS Training and Networking (see Fig. P-28-1), the Regional AIDS Training Network (RATN) has, since 2009, provided grants to its members to implement small, innovative, six- to nine-month HIV and AIDS capacity-building projects that are responsive to emerging evidence and therefore provide the greatest potential for impact in the fight against HIV/AIDS. This initiative achieves six key objectives: innovation, responsiveness, accessibility, institutional capacity strengthening, replicability and sustainability of innovations, and cross-fertilization of ideas. A key pillar of INSTANT interventions is HIV prevention. RATN has so far implemented 19 HIV prevention projects directly and 8 indirectly on various prevention strategies, such as prevention of mother-to-child transmission, the ABC approach (abstinence, being faithful, using condoms), male involvement and voluntary male circumcision, and promotion of sexual and reproductive health. These were achieved using various channels such as community awareness, mass communication, voluntary counseling and testing centers, and development of HIV prevention curricula. Marginalized and key populations including persons with disabilities, most-at-risk populations, orphans and vulnerable children, youth, and women and girls have been reached through these programs.

Method: Needs identification is informed not only by evidence at the national and regional level but also by participatory input. The target communities and relevant stakeholders are involved in formulating solutions. Solutions are evaluated for cost-effectiveness, sustainability, and innovation. INSTANT grants range from $20,000 to $50,000 depending on the scope and reach of the project. The uniqueness of INSTANT granting is that applicants are given mentoring and technical assistance throughout a seven-step process (i.e., concept call, request for proposals, selection and screening, award/contracting, implementation, reporting, and close out). This feedback approach in

Fig. P-28-1: Structure and unique elements of the INSTANT program. M&E = monitoring and evaluation, PMTCT = prevention of mother-to-child transmission.
all of the stages is another way through which INSTANT achieves its capacity-building objective because participants are given technical guidance and best practices that they use to further enhance their proposal-writing and program-designing skills.

**Results:** INSTANT has accounted for a sharp increase in outputs and outcomes. Fifty INSTANT projects have been implemented in 11 countries in East and Southern Africa. More than 3,000 health workers have been trained. The capacities of various stakeholders to respond effectively to the HIV and AIDS pandemic have been enhanced. INSTANT Round One funded 8 institutions and through these grants generated 5 curricula for training managers and health workers in key HIV/AIDS service delivery areas and trained a total of 708 health cadres in various aspects of HIV/AIDS service delivery. INSTANT Round Two trained 1,296 health care workers through the implementation of 23 projects by 17 partner institutions.

**Impact:** Institutions have been strengthened, including their capacity to manage and bid for grants, influence the HIV response nationally, change behavior among the target communities, and have an impact on the trainees receiving the training. HIV responses have been influenced nationally through development of curricula and other tools that were adopted nationally. There has been increased activity in HIV prevention programs at the community level and a trickling of information to other community members. There has been increased delivery at the hospital, leading to a reduction in vertical transmission. There has been a cascading and hence sustainability of interventions through the training-of-trainers approach.

**Key challenges and lessons learned:** Granting at the regional level provides multiplier effects such as south-to-south learning and cross-fertilization of ideas of institutions. Continuous engagement with grantees through mentorship and technical support leads to efficiency, quality, and timeliness in reporting. Participatory approaches lead to greater impact at the community level. Embedding technical assistance and mentoring in granting allows a speedy identification of and response to capacity needs and other implementation challenges. Clear systems to track results for capacity building are necessary to demonstrate results achieved. The INSTANT program is successful because it supports projects that are efficient and effective, provides need-driven capacity-building solutions, is cost-effective, gives ownership to local organizations, creates sustainable interventions, and creates multiplier effects.

**P-29 North–South mentorship for HIV research capacity building in Africa**

**Lawrence Mbuagbaw, Lehana Thabane**

McMaster University, Dundas, Ontario, Canada

**Introduction:** Capacity-building initiatives for HIV research in Africa have evolved beyond workshops and seminars. More and more, research fellowships targeting specific objectives are spreading. A more recent development in this area is the much-needed long-distance mentorship within or without the context of a fellowship. In 2010 the Canadian Institutes of Health Research (CIHR) Canadian HIV Trials Network (CTN) initiated its first international postdoctoral fellowship programme (www.hivnet.ubc.ca/research-services/postdoctoral-fellowships/).

**Methods:** This fellowship is intended for researchers in developing countries who are committed to developing and conducting HIV treatment or prevention research. It lasts one year and involves two face-to-face meetings and frequent email and telephone communication between a Canadian-based mentor and a mentee. These activities are pre-specified and facilitated by the CIHR CTN. The mentee must be affiliated with a local research institution and work with a Canadian-based CTN-approved mentor. We describe here some of the products of this fellowship and the long-distance mentoring activities.

**Results:** Over two years, one mentor (L.T.) worked with three mentees (two in Cameroon, including L.M., and one in Zambia) to complete the following research activities: one qualitative study, a randomised controlled trial, one cross-sectional study and two systematic reviews. Four scientific publications and one book chapter were published, and five invited presentations, four poster presentations and six international conference presentations were given. Other mentee activities included knowledge translation in HIV prevention, systematic reviews and evidence-based medicine, and one mentee (L.M.) is now a co-mentor in the same postdoctoral fellowship program.

**Discussion:** This fellowship has demonstrated the feasibility of goal-oriented long-distance mentorship for knowledge transfer from North to South, using measurable outcomes related to research productivity. This is one case among many and the factors that lead to such output must be carefully considered and studied. It is necessary to understand the effect of mentor–mentee dynamics and characteristics on the mentorship process and its success.

**Conclusion:** This output demonstrates the strength of building mentor–mentee relationships across borders and especially from North to South to enhance research capacity and research productivity for HIV in developing countries. Formal networks linking mentors to mentees with specific goals are warranted and ensure sustainable knowledge transfer from North to South.
However, the characteristics of the mentor and mentee and the dynamics between the two must be considered carefully.

**P-30 Enhancing laboratory capacity of the Kenya AIDS Vaccine Initiative (KAVI) to perform state-of-the-art immune monitoring of HIV vaccine trials**

Julius Oyugi, Bashir Farah, Omu Anzala
University of Nairobi, Nairobi, Kenya

**Background:** The Kenya AIDS Vaccine Initiative (KAVI) has been involved in HIV/AIDS vaccine clinical trials for almost two decades. The establishment of an accredited laboratory has been one of the cornerstones of its achievements as a clinical trials centre. However, since the future of HIV vaccine constructs is still unknown, KAVI has taken the initiative to prepare laboratory assays that will meet the requirements for these vaccines. Therefore, the goals of this study were to (1) train KAVI laboratory staff on current flow cytometry techniques and (2) establish assays able to detect rare, broadly neutralizing monoclonal antibodies and mucosal immunity.

**Method:** In order to achieve the study goals, KAVI laboratory technologists were trained on how to perform HIV antibody assays using mucosal secretions from volunteers. A GlaxoSmithKline fellow from the International AIDS Vaccine Initiative was assigned to KAVI from October 2011 to March 2012. Additionally, four days of theory and hands-on training on a 10-colour flow cytometer were conducted for KAVI technicians.

**Results:** Through training and technology transfer, KAVI is now able to collect and detect mucosal anti-HIV IgA from secretions such as vaginal, cervical, seminal, serum/plasma, salivary, cells either minimal cells through cytobrush or by biopsy, cervical cytobrush and rectal cytobrush. Four KAVI laboratory technologists have been trained on 10-colour flow cytometry and are currently using it for mucosal studies.

**Conclusion:** The training and capacity built through technology transfer at KAVI have prepared the institute for future HIV vaccine assays requiring assaying for HIV-neutralizing antibodies. KAVI is also better placed to assay any future HIV vaccines that may require use of flow cytometry.

**P-31 Harnessing mobile phone usage for HIV and horizontal health systems improvement: prevention of mother-to-child transmission (PMTCT)**

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University of Manitoba, Nairobi, Kenya

Globally just under half a million children are infected with HIV each year, the majority through mother-to-child transmission, and AIDS is now the largest single cause of death for children under 5 years of age. Despite a simple evidence-based proven intervention, most recent data show that only an estimated 61% of pregnant women in Kenya received antiretrovirals for prevention of mother-to-child transmission (PMTCT). Recently, there has been growing interest in the use of mobile telecommunications in health care, and their effectiveness in various capacities has been demonstrated in the developed world and increasingly in the developing world. According to the WHO, use of information and communication technologies, including mobile phone technology, has the potential to impact desired outcomes across all levels of the health system. Short message service (SMS) text reminders have been shown to improve clinical attendance by patients, among other uses. Could mobile phones be used to help improve PMTCT services by way of strengthening health systems? This study aims to determine if mobile phone SMS text messages can demonstrate an improvement in compliance with a known intervention (use of antiretroviral therapy) for PMTCT. In addition it aims to demonstrate that mobile phone technology can be used as an effective tool to strengthen PMTCT health information systems at the facility level. It uses a randomized control trial for unbiased outcome evaluation and a descriptive exploratory qualitative element using in-depth qualitative interviews. Enrolled women are randomly assigned to the intervention or control groups using a random numbers generator. An automated bulk SMS management system sends the intervention group 3 SMS text messages each week reminding them to attend antenatal care (ANC) and to take their drugs. The control group receives the standard of care but no SMS text messages. Blood samples for HIV-1 RNA polymerase chain reaction are taken from infants at 3 intervals: 6 weeks, 14 weeks and 6 months. Participants are reporting more than 4 ANC visits with only 1 or 2 of these at the 2 study sites. Data are also showing that there is poor integration of tuberculosis screening services into the PMTCT program.
**P-32 Clinical features of an HIV-seronegative discordant couple cohort in Nigeria**

**Pam Datong, Evaezi Okpokoro, Ruth Datiri, Grace Choji, Felicia Okolo, Ille Mamman, Sophia Osawe, Alash’le Abimiku**

Plateau State Specialist Hospital, Jos, Nigeria; Plateau State Human Virology Research Centre, Jos, Nigeria; Institute of Human Virology, Nigeria, Abuja, Nigeria; Institute of Human Virology, University of Maryland School of Medicine, Baltimore, Maryland, USA

**Background:** Nigeria remains one of the countries severely affected by HIV/AIDS, with an estimated 281,180 new infections in 2011 despite increased counseling on the risks of transmission, condom use and availability of highly active antiretroviral therapy. Viral subtypes G and CRF02A/G are the predominant drivers of the disease in this part of the world. An effective and safe HIV preventive vaccine is imperative to the ending of this pandemic. The burden and viral diversity of infection has made Nigeria an appropriate site for evaluating HIV vaccines. To date no vaccine trial has been conducted in the country and therefore a cohort appropriate site for evaluating HIV vaccines. To date no vaccine trial has been conducted in the country and therefore a cohort of seronegative discordant couples is being clinically monitored as part of preparedness for future HIV vaccine trials. The overall aim of this study is to develop an HIV clinical research site capable of conducting an HIV vaccine trial using internationally accepted standards with the following specific objectives: (i) to clinically characterize a seronegative discordant couple cohort to document clinical baseline data for the conduct of phase I/II HIV vaccine trials in a subtype G–CRF02A/G region and (ii) to refer those who require medical attention to appropriate clinics to ensure that potential participants are fairly healthy.

**Methods:** An observational cohort study was initiated in October 2011 at Plateau State Human Virology Research Centre, Jos, and its satellite sites to enrol, document and monitor the clinical status of HIV-negative serodiscordant couples in central Nigeria as part of vaccine preparedness. Medical history of fever, headache, nausea/vomiting, diarrhea, sore throat, easy fatigue-ability, cough or difficult breathing was obtained from the seronegative participants by experienced medical personnel to establish or exclude common endemic infections or diseases like malaria, acute respiratory infections and diarrhea. History of prolonged cough productive of sputum with or without blood and associated with weight loss to suggest tuberculosis (the most common opportunistic infection in partners) was obtained. The World Health Organization syndromic management of sexually transmitted diseases based on algorithms of presenting symptoms/signs was used to diagnose and treat participants who presented with symptoms of STIs. In addition, a careful general examination, particularly for pallor, jaundice, cyanosis, finger clubbing, facial or pedal edema, generalized skin lesions, palpable lymph nodes, body temperature and weight, was done. This was followed by a systemic medical examination with interest in the pulse volume/rate, blood pressure, heart sounds, breathing rate and breath sounds. An abdominal examination was also done for any abdominal scars or pain and palpable liver or spleen. Pelvic examinations were performed for urethral or vaginal discharge, genital ulcers or warts, painful inguinal lymph nodes and lower abdominal pain only when a participant had a history of an STI. The following safety laboratory tests were carried out on blood specimens collected on study visits: full blood counts and liver and kidney function tests. Those participants who required further medical evaluation as a result of the medical examination and/or laboratory tests were promptly referred.

**Results:** A total of 315 participants have so far been enrolled into the study. Their mean age was 38 years (19–65 years) with a female to male ratio of 1:1 (157:158) and all them were in a marital relationship. Twenty-one (6%) enrollees had prolonged cough (≥ 2 weeks), with 12 (57%) producing sputum, but none were found to have tuberculosis after further evaluation. Thirty-three (21%) women and 13 (8%) men were treated for vaginal and urethral discharges respectively while 10 (3%) of the participants had genital ulcers. Hypertension (systolic ≥ 140 mm Hg and/or diastolic pressure ≥ 90 mm Hg or established hypertensive on treatment) was found in 107 (34%). The proportion of those found to be hypertensive is similar to that of most studies done in the country. Of the 776 hemoglobin concentration tests done, 103 (13%) (from 60 participants) had levels <12 g/dL; 51 (85%) of the anemic participants were female and 9 participants, 6 of whom were females (66%), were referred for further tests and treatment of anemia (hemoglobin ≤10 g/dL). Two female participants had uterine bleeding and needed surgery. The majority

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**Table P-32-1: Results of safety laboratory tests**

<table>
<thead>
<tr>
<th>Test</th>
<th>Range</th>
<th>95% confidence interval</th>
<th>Laboratory reference range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin concentration, g/dL</td>
<td>3.4–17.7</td>
<td>13.44–13.91</td>
<td>12–16</td>
</tr>
<tr>
<td>White blood cell count, ×10³/L</td>
<td>2.9–9.0</td>
<td>4.87–5.33</td>
<td>3.5–11</td>
</tr>
<tr>
<td>Platelet count, ×10⁹/L</td>
<td>63–498</td>
<td>235.67–246.68</td>
<td>130–400</td>
</tr>
<tr>
<td>SGPT (ALT), IU/L</td>
<td>3–314</td>
<td>28.28–30.41</td>
<td>7–55</td>
</tr>
<tr>
<td>SGOT (AST), IU/L</td>
<td>5–191</td>
<td>28.90–30.81</td>
<td>14–59</td>
</tr>
<tr>
<td>Bilirubin, µmol/L</td>
<td>2–29</td>
<td>11.13–11.95</td>
<td>0–17</td>
</tr>
<tr>
<td>Creatinine, µmol/L</td>
<td>2–99.9</td>
<td>67.60–70.23</td>
<td>50–118</td>
</tr>
</tbody>
</table>

ALT = alanine transaminase, AST = aspartate transaminase, SGOT = serum glutamic oxaloacetic transaminase, SGPT = serum glutamic pyruvic transaminase.
of the safety laboratory results were within normal reference values, except for some outliers that were found to be normal on subsequent testing (Table P-32-1).

Conclusion: Our study indicated that the clinical examination complemented by safety laboratory tests of a relatively healthy HIV-seronegative discordant couple cohort provides important baseline information for the preparation and conduct of HIV vaccine phase I/II trials in a particular population. The routine medical care also built the capacity of research medical staff who were mentored by the study physician and provided an added incentive for volunteer retention.

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P-33 Experiences and gaps in the provider-initiated HIV care delivery model in a large HIV clinic in south western Uganda

Peter Ssebutinde, Winnie Muyindike
Canada–Africa Prevention Trials (CAPT) Network, Mbarara site, Kampala, Uganda

Introduction: HIV disease has all the features of a chronic condition. People with HIV/AIDS can live longer, healthier lives because of advances in the treatment of HIV infection. However, longer lives are associated with increased prevalence of adverse effects of the HIV infection itself, the drugs used to treat HIV and the concurrent medical conditions that would have occurred in the absence of HIV. These long-term complications have put HIV infection in the realm of chronic diseases rather than infectious diseases, which usually respond to short-term clinical interventions. Effective management of chronic diseases in the primary care setting requires the coordination of interventions that occur at the level of the clinical services, the community supports for those clinical services and the individual patient. While clinical services begin in the primary care clinic, community support is needed and the patient must be engaged to enhance self-management. The chronic care model (Fig. P-33-1) conceptualizes how these factors impact the clinical outcome of chronic disease management. The chronic care model, if adopted, will be used to provide proper chronic care services. The provision of chronic care to people living with HIV/AIDS at the Immune Suppression Syndrome Clinic of the Mbarara Regional Referral Hospital is provider initiated, programmed and sustained with little or no input from the communities. Though active models of chronic care service delivery are rarely available in low-income countries like Uganda, HIV, like any other chronic noncommunicable disease, requires a continuous mode of care. More than 90% of the patients/clients are peasant farmers who are living on “under a dollar per day” and they have to travel long distances (80–90 km) involving high transport costs to come to the clinic for every appointment. No chronic care model has been developed to encourage patients and the other stakeholders to participate in designing and developing suitable and sustainable service delivery systems. It is important that all HIV/AIDS health care providers optimize therapeutic outcomes by practising in a setting that recognizes the social and psychological needs of patients and the role of other stakeholders while providing expert HIV-specific care consistent with routine chronic care. The aim of the study was to identify the existing gaps in current chronic care and the factors that influence access and use of chronic care services by HIV/AIDS patients attending the clinic, focusing on describing the experiences and challenges of chronic HIV/AIDS care providers, explaining the major challenges and fears of people living with HIV/AIDS and describing the role of other stakeholders.

Methods: The study was conducted among HIV-infected patients ≥ 18 years who were seeking chronic HIV care from the Mbarara regional referral HIV clinic for ≥ 12 months. A cross-section of patients was given semi-structured questionnaires for collection of demographic information and information about their experiences and challenges with respect to HIV care. Twelve key informants were purposively selected from among the HIV clinic service providers for in-depth interviews. Data collected from the in-depth interviews were manually and thematically analyzed.

Results: A total of 87 patients were interviewed, 62 (71.3%) of whom were females, with an average age of 40.5 years (range...
### Table P-33-1: Baseline characteristics of patients receiving chronic care at the Immune Suppression Syndrome (ISS) clinic

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>62</td>
<td>(71.3)</td>
</tr>
<tr>
<td>Males</td>
<td>25</td>
<td>(28.7)</td>
</tr>
<tr>
<td><strong>Levels of education attained by participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary level</td>
<td>52</td>
<td>(59.8)</td>
</tr>
<tr>
<td>Secondary level</td>
<td>19</td>
<td>(21.8)</td>
</tr>
<tr>
<td>University</td>
<td>1</td>
<td>(1.1)</td>
</tr>
<tr>
<td>Other tertiary level</td>
<td>7</td>
<td>(8.0)</td>
</tr>
<tr>
<td>None</td>
<td>8</td>
<td>(9.2)</td>
</tr>
<tr>
<td><strong>Number of years in the ISS clinic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 years</td>
<td>11</td>
<td>(12.6)</td>
</tr>
<tr>
<td>5 years</td>
<td>72</td>
<td>(82.8)</td>
</tr>
<tr>
<td>10 and above years</td>
<td>4</td>
<td>(4.6)</td>
</tr>
<tr>
<td><strong>Social level of disclosure of HIV status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Children</td>
<td>67</td>
<td>(77.0)</td>
</tr>
<tr>
<td>Parents</td>
<td>7</td>
<td>(8.0)</td>
</tr>
<tr>
<td>In-laws</td>
<td>2</td>
<td>(2.3)</td>
</tr>
<tr>
<td>Siblings</td>
<td>5</td>
<td>(5.7)</td>
</tr>
<tr>
<td>Others (friends and workmates)</td>
<td>6</td>
<td>(6.9)</td>
</tr>
<tr>
<td><strong>Spouse’s HIV status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>7</td>
<td>(8.0)</td>
</tr>
<tr>
<td>Positive</td>
<td>58</td>
<td>(66.7)</td>
</tr>
<tr>
<td>Not tested</td>
<td>22</td>
<td>(25.3)</td>
</tr>
<tr>
<td><strong>Martial status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>30</td>
<td>(34.5)</td>
</tr>
<tr>
<td>Not married</td>
<td>39</td>
<td>(44.8)</td>
</tr>
<tr>
<td>Separated</td>
<td>18</td>
<td>(20.7)</td>
</tr>
<tr>
<td><strong>Number of years in a stable sexual relationship/marriage (n= 30)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 5 years</td>
<td>5</td>
<td>(16.7)</td>
</tr>
<tr>
<td>1–5 years</td>
<td>23</td>
<td>(76.7)</td>
</tr>
<tr>
<td>Less than 12 months</td>
<td>2</td>
<td>(6.6)</td>
</tr>
</tbody>
</table>

### Table P-33-2: Major challenges faced by the 87 study participants at the ISS Clinic

<table>
<thead>
<tr>
<th>Challenge</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delays or spending a lot of time at the clinic</td>
<td>25</td>
<td>(28.7)</td>
</tr>
<tr>
<td>Rude health workers</td>
<td>5</td>
<td>(5.7)</td>
</tr>
<tr>
<td>Persistent high transport costs</td>
<td>6</td>
<td>(7.0)</td>
</tr>
<tr>
<td>Disclosure of one’s status by another client at the clinic</td>
<td>5</td>
<td>(5.7)</td>
</tr>
<tr>
<td>Lack of drugs for other infections</td>
<td>2</td>
<td>(2.3)</td>
</tr>
<tr>
<td>Side effects of the antiretroviral therapy</td>
<td>2</td>
<td>(2.3)</td>
</tr>
<tr>
<td>Forgot to swallow pills</td>
<td>6</td>
<td>(6.9)</td>
</tr>
<tr>
<td>Indifferent responses</td>
<td>36</td>
<td>(41.4)</td>
</tr>
</tbody>
</table>

26–62 years) (Table P-33-1). The major challenges faced by patients included long waiting hours, overcrowding at the clinic, and a high clinician:patient ratio (Table P-33-2). Only 10.3% sought help from the counselors; 57% sought divine intervention and another 10.3% simply braved the situation while 9.2% resorted to survival mechanisms of borrowing from relatives and friends and selling their garden produce as a means of coping with the challenges, and 35% were indifferent. The exploration of service providers’ experiences showed that the clinic had developed into a comprehensive and highly specialized unit with sophisticated equipment able to do CD4 counts, viral load counts, DNA/PCR tests and all the other blood chemistry tests; however, there were gaps identified in the clinic in the areas of social work and rehabilitation of HIV/AIDS patients and integration and linkage of the HIV legal framework to HIV chronic care. The regional HIV clinic runs on a purely provider-initiated approach, without involvement from the community or other stakeholders, according to the service providers.

**Conclusion:** Provider-initiated HIV care is good; however, patients face several challenges. This vacuum created by minimal community involvement and the lack of involvement of the other stakeholders affects the quality of chronic care. The adoption of the chronic care model would greatly improve the quality of HIV chronic care. These interventions should be considered as part of strategies to improve HIV care by changing provider performance.

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**P-34 Nurturing a new generation of scientific writers in Soweto, South Africa**


Perinatal HIV Research Unit, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

**Introduction:** Sub-Saharan Africa bears the burden of infectious diseases like HIV and tuberculosis. Addressing these public health challenges requires knowledge dissemination of evidence-based medicine. Research centres often rely on PhD or postdoctoral candidates to produce the publications required for such education. However, compared to the average of 200 annual PhD graduates per million of the total population in developed countries, South Africa generates a mere 26 doctorates per million of the total population yearly, with resultant limitations on publication outputs. Financial constraints, the paucity of doctorally qualified supervisors and certain government policy regulations are examples of obstacles in the pathway between postgraduate completion and doctoral enrolment. Therefore, there exists a need to build publication capacity and create scientific
Results: Ten applicants were accepted into the programme. Four (1 medical doctor and 3 master’s graduates employed as managers) completed manuscripts and conference abstracts that addressed programmatic male circumcision safety data, outcomes of HIV-infected patients with advanced immune suppression, refusal to seek HIV testing and sexual behaviour of HIV-discordant couples. Reasons for not completing manuscripts included resignation from the organisation (n = 2), withdrawal from the programme (n = 2) and difficulty with writing (n = 2).

Conclusion: Even within a resource-constrained setting with a busy agenda, it was possible to provide the necessary training and coaching that resulted in individuals at the programme-management level producing manuscripts for publication and contributing to knowledge-generating capacity. The programme provided participants opportunities for personal development, networking with senior researchers and career advancement.

P-35 Building regional clinical trial capacity through good clinical practice (GCP) training: progress, prospects and challenges

Gaudensia Mutua, Jacquelyn Nyange, Bashir Farah, Omu Anzala

Kenya AIDS Vaccine Initiative (KAVI), University of Nairobi, Nairobi, Kenya

Introduction: Regionally there is only a very small number of highly trained investigators, nurses and data and laboratory staff with the knowledge and experience required to supervise and conduct clinical trials. In 2010, the Kenya AIDS Vaccine Initiative (KAVI) set out to establish itself as a center of excellence for the training and equipping of health care professionals with the skills required for the conduct of clinical trials in the region.

Methods: KAVI designed a two-day course on good clinical practice, which was piloted locally in Kenya in 2011. With feedback from the first set of trainees, KAVI amended and re-packaged the course for a regional audience. The course was aimed at a diverse range of clinical trial staff, including research nurses, data managers, study physicians and laboratory scientists. The course was advertised in a local newspaper and posted on the KAVI website. Facilitators also reached out to and networked with staff from Muhimbili and Makerere universities.

Results: Response to the advertisement in the newspaper and on the website was poor and only resulted in one training session being conducted in Kenya, which was attended by 16 trainees. The staff of Muhimbili and Makerere universities were interested in the training but did not have the budget for it. Training was therefore subsidized for the two sites using funds.
from the Global Health Research Initiative grant. Fifty-three staff from Muhimbili and 20 from Makerere were trained. In all three training sessions, local staff were incorporated as facilitators as part of a mentorship program. Feedback from trainees has been positive and has resulted in invitations to train research staff in Tororo (Uganda) and Mbeya and Mwanza (Tanzania). KAVI has also received a request to conduct annual training of new staff at both Muhimbili and Makerere. KAVI has recently received a request to train research staff in Mozambique at a site that will soon conduct its first HIV vaccine study.

**Discussion:** Increasingly, sponsors and investigators have shown an interest in conducting clinical trials and other health-related research in resource-limited settings in Africa. Disparities exist in the clinical trial capacity in high-income versus middle- and low-income countries. However, it is critically important for health-related research to be conducted according to internationally accepted standard regardless of the setting. It is also important for investigators to nurture South-to-South linkages and to develop training programs that are based on culturally relevant experiences. Besides research physicians, the program was able to target different cadres of research staff including data, laboratory and nursing staff. Sustainable research capacity building requires training individuals at multiple levels within a supportive institutional infrastructure. Training activities can foster capacity building to support the research needs of local researchers.

**Conclusion:** The expansion of this training program has been greatly enhanced by word of mouth. Trainees who have benefitted from the training have recommended KAVI to other research units. Funding for the program is supported by a grant that extends until 2014. Sustainability of the training program will therefore depend on supporting the local facilitators mentored at the research sites that have benefitted from the training. By targeting university staff and public institutions, KAVI hopes to maintain a captive audience that will form the next generation of researchers and facilitate integration into the university training syllabus.

**Design:** This was an analytical cross-sectional study on a census of 3457 patients enrolled on ART for two months and longer.

**Methods:** We conducted a retrospective electronic data review with logistic multivariate analysis to assess the effect of the community drug distribution points (CDDP) programme on retention of ART patients compared to facility model.

**Results:** Loss to follow-up was four times higher in the facility arm with 215 (16.5%) of 1302 patients, compared with 103 (4.28%) of 2155 CDDP-based clients (p < 0.0001). Fewer deaths were reported in the CDDP arm (84 [3.9%]) compared with the facility arm (77 [5.7%], p = 0.008).

**Conclusion:** For large-scale ART providers in resource-limited settings, the CDDP model has better patient retention outcomes evidenced by the four times lower loss to follow-up and fewer deaths.

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**P-37** A study of the potential benefit of integration of quality sexual and reproductive health (SRH) with HIV care using a “stepped wedge” design

**Christine Katusiime, Walter F. Schlech III, Jolly Beyeza-Kashesya, Rosalind Parkes-Ratanshi, Andrew Kambugu**

**Introduction:** Provision of robust sexual reproductive health (SRH) care in HIV-infected persons is effective in preventing the spread of HIV infection to partners and transmission from mothers to children. Integrating SRH and HIV care in resource-limited settings may be an effective strategy for improving outcomes for both conditions. Additionally, screening HIV-infected persons for SRH ailments has the advantage of identifying HIV-infected persons continuing to engage in high-risk sexual behavior. Currently SRH care for HIV-positive patients is often outsourced to other providers with little coordination. Our aim will be to establish the potential value of quality integrated modular SRH/ HIV care within HIV clinics in resource-limited settings.

**Design:** This was an analytical cross-sectional study on a census of 3457 patients enrolled on ART for two months and longer.

**Methods:** We conducted a retrospective electronic data review with logistic multivariate analysis to assess the effect of the community drug distribution points (CDDP) programme on retention of ART patients compared to facility model.

**Results:** Loss to follow-up was four times higher in the facility arm with 215 (16.5%) of 1302 patients, compared with 103 (4.28%) of 2155 CDDP-based clients (p < 0.0001). Fewer deaths were reported in the CDDP arm (84 [3.9%]) compared with the facility arm (77 [5.7%], p = 0.008).

**Conclusion:** For large-scale ART providers in resource-limited settings, the CDDP model has better patient retention outcomes evidenced by the four times lower loss to follow-up and fewer deaths.

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**P-36** Community antiretroviral therapy (ART) delivery model for high retention of patients on ART—The AIDS Support Organization (TASO) operational research findings in east and central Uganda, a resource-limited setting

**Denis Mpiima, J. Birungi, S. Canters, C. Luzze**

The AIDS Support Organization (TASO) Jinja, Jinja, Uganda

**Objective:** This study aimed to assess retention outcomes from the community and facility antiretroviral therapy (ART) delivery models.

**Design:** This was an analytical cross-sectional study on a census of 3457 patients enrolled on ART for two months and longer.

**Methods:** We conducted a retrospective electronic data review with logistic multivariate analysis to assess the effect of the community drug distribution points (CDDP) programme on retention of ART patients compared to facility model.

**Results:** Loss to follow-up was four times higher in the facility arm with 215 (16.5%) of 1302 patients, compared with 103 (4.28%) of 2155 CDDP-based clients (p < 0.0001). Fewer deaths were reported in the CDDP arm (84 [3.9%]) compared with the facility arm (77 [5.7%], p = 0.008).

**Conclusion:** For large-scale ART providers in resource-limited settings, the CDDP model has better patient retention outcomes evidenced by the four times lower loss to follow-up and fewer deaths.
that of a chronic disease in most industrialized countries, with a lifespan approaching population norms in people on effective ART. Even in resource-limited settings in Africa, the introduction of effective highly active ART has resulted in better health outcomes, most notably in the reduction of MTCT, where timely therapy during pregnancy and breastfeeding has been shown to reduce the risk of MTCT of HIV to <2%, down from rates of 15%–30% without treatment. With more effective HIV therapies has come an increased recognition of the reproductive and sexual health rights of people living with HIV, resulting in publications by the World Health Organization and the Joint United Nations Programme on HIV/AIDS supporting reproduction as a basic human right of people living with HIV. In Canada, this paradigm shift has led to the recent publication of the Canadian HIV Pregnancy Planning Guidelines, to provide information to health care providers to allow them to assist Canadians living with HIV to make reproductive health decisions using advanced risk-reduction technologies available in most industrialized countries, such as sperm washing and intrauterine insemination. In many African countries, where over 60% of people infected with HIV are of child-bearing age, the greater acknowledgement of the fertility desires and reproductive rights of people living with HIV has been a welcome change, given that the desire to have large families is deeply ingrained; children are needed to look after the elderly and to participate in a largely agrarian economy. Research suggests that ~20% of people living with HIV in Uganda plan to conceive, despite their HIV status. Given that most resource-limited countries in Africa have adopted guidelines for the initiation of ART at CD4 counts < 350 cells/mL, many HIV-positive individuals having unprotected sex for the purpose of procreation are not on ART. In the case of serodiscordancy between couples, the uninfected partner is at risk of infection during conception. In the absence of ART, the rate of HIV transmission between serodiscordant couples is estimated to be 5%–10% per year. The decision of serodiscordant couples to have children therefore carries significant risks that are not adequately addressed by existing ART guidelines in resource-limited settings. Accumulating level 1 evidence from randomized controlled trials suggests that a dramatic reduction in HIV transmission among heterosexual serodiscordant couples is feasible with both effective ART of the infected partner and pre-exposure prophylaxis of the uninfected partner, although not all pre-exposure studies (i.e., Preexposure Prophylaxis Trial for HIV Prevention among African Women (FEM-PrEP)) show positive results. Specifically, a larger randomized trial in serodiscordant couples (n = 1763 couples) showed that early effective ART of the positive partner reduces the risk of HIV transmission to the uninfected partner by 96% (to 0.1 cases/100 person-years), as compared to delayed treatment initiated at CD4 < 250 cells/mL. Most recently at the 19th Conference on Retroviruses and Opportunistic Infections in 2012, pre-exposure prophylaxis of the uninfected partner with daily oral tenofovir or tenofovir and emtricitabine was also shown to reduce the risk of HIV acquisition by over 70% among heterosexual serodiscordant couples where the infected partner was not on ART, in both committed relationships and in heterosexual single men and women. In pre-exposure prophylaxis trials, treatment adherence has been shown to be a key determinant of treatment effectiveness, which notably was most effective among men and women in committed relationships, approaching 90% risk reduction. Importantly, poor treatment adherence may also explain the negative results observed in the FEM-PrEP study, where adherence was < 35% in women in the treatment arm who became infected.

Methods: This is a prospective operational research study providing integrated screening and care for sexually transmitted infection (STI), pregnancy and cervical cancer to HIV-infected patients and their partners using a “stepped wedge” design. Our HIV center will develop a modular SRH module program. Six network sites will be randomly assigned to introduce the module (3 sites) or follow their standard approach to SRH care (3 sites). A the end of 6 months of study the SRH module will be “rolled out” to the 3 control sites and all 6 sites will be followed for a further 6 months of study. Outcomes during the study will include rates of STIs, pregnancy (planned and unplanned), MTCT of HIV, cervical dysplasia, transmission to discordant partners, and CD4 count and viral load in HIV-infected patients.

Study sites: Infectious Diseases Institute, Kampala, Uganda; Immune Suppression Syndrome Clinic, Mbarara, Uganda; The AIDS Support Organization in Uganda (Jinja and Gulu clinics); Uganda Virus Research Institute, Entebbe, Uganda; Edendale Hospital, Pietermaritzburg, KwaZulu-Natal, South Africa; and University of Nairobi Clinic, Nairobi, Kenya.

Results: After 6 months of follow-up, outcomes in the centers with integrated SRH/HIV care will be compared to the outcomes in the centers with standard care. We hope to see decreases in STI rates, cervical dysplasia, and HIV transmission as well as improved responses to ART in those on ART who have access to the SRH module. These outcomes would improve at the control sites during the 6 months of study following implementation at those sites. We also hope to prove that new investment in and reorganization of SRH activities is a cost-effective intervention in HIV clinics in resource-limited settings.
**P-38 Cost effectiveness of HIV prevention strategies in Uganda**

Joseph Bukulu Sempa, Mohammed Lamorde, Mark Sennono, Yuka Maname, Andreas Kuznik, Barbara Castelnuovo, Andrew Kambugu, et al.

**Background:** HIV/AIDS is a leading cause of morbidity and mortality in sub-Saharan Africa. Randomized trials demonstrate that medical male circumcision prevents HIV acquisition in uninfected males and that antiretroviral therapy (ART) can prevent horizontal and vertical HIV transmission. However, health economics data on these interventions are scarce in resource-limited settings. This abstract outlines three health economics studies on prevention strategies for HIV that were conducted at the Infectious Diseases Institute (IDI), Kampala.

**Methods:** Study 1: Using actual costs at IDI outreach sites, we evaluated the cost implications of medical male circumcisions for HIV prevention when performed using reusable equipment that is sterilized after each use versus using commercial single-use disposal kits. Study 2: We evaluated the cost-effectiveness of different antiretroviral strategies for prevention of mother-to-child transmission (PMTCT) versus lifelong ART in pregnant women using a decision-based analytic model. Study 3: We evaluated the cost-effectiveness of earlier initiation of ART at CD4 count thresholds <350 cells/mL versus <250 cells/mL using a decision-based analytic model. For the cost-effectiveness analyses in studies 2 and 3, we evaluated the disability-adjusted life years (DALYS) and life expectancy. All the analyses were done from the perspective of the Ugandan national health care system. All cost and benefits were discounted at an annual rate of 3%. Interventions were considered highly cost-effective using the recommended one-time per capita gross domestic product threshold of US$490 reported for Uganda.

**Results:** Study 1: Using reusable circumcision kits results in a net saving of US$734–US$1234 (46%–59%) per procedure. Study 2: Compared with single-dose nevirapine, dual therapy and no therapy, 18 months of ART averted 5.21, 3.22 and 8.58 DALYS, respectively, at a cost of US$446, US$599 and US$34 per DALY averted. Lifetime ART averted 19.20, 11.87 and 31.60 DALYS, respectively, at a cost of US$205, US$354 and US$172 per DALY averted. Study 3: Lifetime treatment costs were $4,300–$5,248 for early initiation and $3,940–$4,435 for delayed initiation. The cost/DALY averted of the early versus delayed start ranged from $260 to $270.

**Conclusions:** In Uganda, substantial cost reductions may be achieved by adopting reusable circumcision kits; ART for PMTCT was found to be highly cost-effective, even if continued over the patients’ lifetimes, and initiation of ART using the recently revised CD4 threshold of 350 cells/mL is also highly cost-effective. Resources should be mobilized to expand access to these interventions.

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**P-39 Canadian HIV Vaccine Initiative (CHVI) Research and Development Alliance Virtual Community:** connecting you to the Alliance!

Tanya Merke Epp

Canadian HIV Vaccine Initiative (CHVI) Alliance Coordinating Office, Winnipeg, Manitoba, Canada

A joint commitment between the Government of Canada and the Bill & Melinda Gates Foundation, the renewed Canadian HIV Vaccine Initiative (CHVI) aims to support and amplify national and global HIV vaccine research and development efforts. As the cornerstone of this initiative, the CHVI Research & Development Alliance is an emerging partnership among Canadian funders, national and global researchers and community organizations, the vaccine industry and the supporting Alliance Coordinating Office (ACO), which are working collaboratively to amplify Canada’s impact on global HIV vaccine efforts. The ACO is building on existing collaborations and augmenting capacity building through the creation of the CHVI & D Alliance Virtual Community (Alliance VC). The Alliance VC is being developed in collaboration with representatives of an Alliance VC Advisory Group. The Alliance VC is a private internet-based community designed for leaders in HIV vaccine research to collaborate, communicate, and share research and information. Members of CHVI-funded project teams and programs will automatically have secure access to this virtual community, which will provide, among other things, a virtual meeting space for collaborations, hosting of “private” interest/project groups, an online collaborative document creation and editing tool, training, teleconferences, webinars, resource material, and a Canadian researcher database. In this session the ACO will offer a live demonstration of Alliance VC features, tools, and the range of possible uses of the private committee workspaces available to all members of the CHVI R&D Alliance. The demonstration will be followed by a hands-on instructional workshop where participants will learn how to register, login, and begin using the Alliance VC. This session will help participants explore how this technology will connect them with the Alliance. Participants are encouraged (but not required) to bring their laptop computers for this session.

**P-40 Exceptional leadership**

Allan Ronald

University of Manitoba, Winnipeg, Manitoba, Canada

All of us are expected and even required to be leaders as scientists, health providers, and persons with influence. Most of us have the potential and the desire to be exceptional in our communities, at work and elsewhere. An excellent return on the investment others
have made to “make” me can enable me to leave the world with more than I’ve taken out of it. Becoming an exceptional leader can be intentional and learned in the course of one’s life. Zenger and colleagues have recently published a book entitled *How to Be Exceptional*. Some of their observations resonate with my own experience through the past five decades as a leader both learning and training. They provide evidence that building on one’s strengths is far more likely to enable exceptionalism than obsessing on one’s weaknesses. Everyone has weaknesses that need to be recognized and may need to be addressed but rarely, despite intense efforts, can these weaknesses become strengths. However, strengths can be further developed and enable exceptional leadership. Strategies for thinking about this in your own development will be identified and discussed.
Where do we go from here?
Recommendations from the Afri-Can Forum

The following recommendations were gleaned from the Forum’s wrap-up session (see online Appendix S-28), as well as from other Forum discussions and the post-Forum evaluations.

Specific recommendations

1. Inter-team collaborations

Forum participants identified many synergies and noted that a number of the teams’ projects were addressing related research questions. For example, teams in every region are following cohorts of serodiscordant couples. One participant suggested that they work collectively to explore cross-cohort questions of population genetics relevant to vaccine discovery. Another participant mentioned the need to explore strategies for increasing male partner involvement in HIV prevention.

It is recommended that there be a focused effort to encourage and identify opportunities for inter-team collaboration.

2. Ongoing communications

At the Forum, there was a lot of enthusiastic networking and a strong feeling of being part of a broad-based network. This was seen as the most valuable aspect of the Forum and something that needs to be maintained.

It is recommended that the Forum participants be given opportunities to continue communicating and networking with each other, specifically through

• a series of virtual inter-team meetings
• the maintenance of a user-friendly website (or Facebook page) through which all participants can communicate with each other collectively and/or individually
• a follow-up face-to-face meeting in Africa, to be held in a year’s time

3. Mentoring

The importance of helping young scientists develop into independent researchers was noted.

It is recommended that the teams’ broad base of expertise be used for the purpose of mentoring young scientists, including the provision of seed funding for such mentoring efforts.

4. Ongoing infrastructure support

It was stressed that ending a funding stream is extremely disruptive and can be a severe setback to a site’s capacity to conduct research.

It is recommended that the Global Health Research Initiative (GHRI) and the Canadian Institutes of Health Research (CIHR) make available opportunities and strategies for maintaining the capacity-building and team-building outcomes that are occurring as a result of current projects.

5. Salaries of African research investigators

Canadian research funding is often the only source of income for African co-investigators.

It is recommended that the Canadian funding agencies permit African co-investigators to receive payment for their work on research projects.

General recommendations and suggestions

6. An effort should be made to assess the collective readiness of the Canadian HIV Vaccine Initiative (CHVI)—affiliated teams to participate in a large vaccine efficacy trial.

7. The CHVI is encouraged to continue its practice of integrating social science and biomedical science. Additional efforts should be made to bridge the gap between these two sciences.

8. The function of the Immunopaedia website (www.immunopaedia.org.za) should be expanded to include practical immunological processes for collecting and processing samples (such as those from mucosal sites and some immunological assays).
9. The usability and user-friendliness of the CHVI’s Alliance Coordinating Office (ACO) website should be expanded as a communications tool for the groups.

10. From the interagency panel discussion, it is recommended

- that the GHRI teams continue to work closely with international networks (e.g., International AIDS Vaccine Initiative [IAVI]) to further strengthen local sites’ capacity to conduct research on key populations (especially young people, men who have sex with men [MSM], serodiscordant couples and mobile populations)
- that the Canadian government agencies continue to engage African governments, regulatory agencies and national HIV bodies in their planning and programming, and that they expand that involvement
- that the GHRI teams and the large study teams work with the proposed Cape Town HIV Vaccine Laboratory, which aims to build a stronger African infrastructure for large-scale studies and to facilitate career development of African laboratory scientists

11. From the session on study management, it is recommended that the teams find ways to synchronize their study management procedures to help alleviate some of the administrative burdens faced by sites, which currently must follow a different set of management procedures for each study. This should also include improvements to institutional approval and contract processes.

12. Appreciation was expressed for the current teams’ “African-led, Canadian-enabled” approach to conducting research. It is recommended that this approach be maintained and strengthened, since it is important for ensuring that the results will continue to be relevant to local needs and that the outcomes can be more easily moved from theory into practice.
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