

**4th IAS Conference on HIV Pathogenesis, Treatment and
Prevention
Rapporteur Summaries and Closing Session
International AIDS Society
and Australasian Society for HIV Medicine
July 25, 2007**

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JOHN KALDOR, Ph.D.: Good afternoon, everyone, and welcome to the last content session of what I think you'll all agree has been a fantastic three days of conference and, as one of the members of the organizing committee, I must say it's been such a fantastic pleasure to see it all unfold and to feel the hard work over a number of years paying off and it all taking shape.

I'm John Kaldor from Sydney and it's my pleasure to co-chair the Rapporteur Session with Craig McClure from the Chief Executive Office of the International AIDS Society.

So, you'll be hearing summaries from three chief rapporteurs, Track A, Track B, Track C, and then a community statement. And each of the track rapporteurs will have 15 minutes to describe the work of themselves and their teams and the community statement will be of five minutes' duration. And this session will then be followed by the official closing ceremony.

So, I'd like to start off by introducing Gilda Tachedjian. Gilda is the head of the Molecular Interactions Group at the Burnet Institute in Melbourne. And she is also an RD Wright Fellow of the National Health and Medical Research Council of Australia and is a honorary single lecturer at the Monash University in Melbourne. So, I'd like to hand over to Gilda for the Track A Summary.

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[Applause]

GILDA TACHEDJIAN, B.SC, Ph.D.: Thank you, John. I would like to start by first congratulating Demi and Casella and [inaudible], the co-chairs of Track A for putting together an outstanding basic science program which has covered many of the pertinent areas in basic biology of HIV replication and pathogenesis. Secondly, I'd like to acknowledge and thank my assistant rapporteurs, Eric Arts, Anthony Gerowoski [misspelled?], and John Saunders [misspelled?], who all did a magnificent job covering the basic science sessions. And last, but not least, I would like to thank the IAS staff for providing us with the support during this challenging rapporteur process. And Courtney from NCHECR for providing us with chocolate to keep us going.

So, what are we covering in this presentation is the new and exciting developments presented at this conference on new drug targets, and therapies, which has come a long way from the traditional reverse transcriptase and protease targets, novel drug resistance mechanisms, intracellular immunity to HIV, microbicides and mucosal immunity in transmission, and immunopathogenesis.

The session on new drug targets and compounds highlighted novel approaches for inhibiting HIV replication. Of interest are strategies that target protein-protein interactions, which is a challenging area in drug design. In

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this regard, it's more [inaudible] identified by virtual screening, blocks interaction between tach [misspelled?] and a host cell protein called protein phosphatase 1 and inhibits HIV replication in cell culture. Interestingly, protease inhibitors, including darunavir, can also inhibit protein protein reactions between the two subunits of the HIV protease. These inhibitors do not abrogate generalization of the preformed protease, hymodyma [misspelled?], and are therefore likely to target the gate hole in betaprotease. There also some oily biviral [misspelled?] infusion inhibitors with a distinct mechanism of action to infervitide have been identified and would be a welcome addition to the treatment armory.

Data was presented on the second-generation maturation computer of Vaviramech, with reduced protein binding, which is under development. And a novel class of RT inhibitors that bind magnesium ions at the [inaudible] site. A novel VPU ion channeling inhibitor, [inaudible] 225 was described that specifically inhibits HIV replication microphages and today Rubin Harris presented data showing that like potent antiviral drugs, Atrobex 3G forces the virus to introduce mutations in [inaudible] in order to replicate. These data provide strong evidence justifying the development of compounds that modulate 3GVC [misspelled?] interaction.

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An exciting and evolved strategy presented by John Rossi, is the development of a triple R Vector for HIV gene therapy. To prevent the emergence of HIV resistance, this vector expresses a combination of three types of RNAs. A nuclear localizing TAR decoy, a ribosome designed to knock down expression of the host cell receptor CCR5, and a short [inaudible] RNA which is processed in the cell to siRNA and targets the RNA expressing tetinriv [misspelled?]. Autolocity 434 positive hemopoetic stem cells or T-cells are transduced with this vector and the cells are re-infused into patients. FDA approval has been obtained to conduct clinical trials for the triple R's constructing HIV infected patients. The outcome of this trial will be of tremendous interest in ascertaining the feasibility of siRNA-based gene therapy for HIV-AIDS and whether this strategy is capable of preventing the emergence of drug resistance escape mutants, which remains a challenging goal, as articulated by Ben Burkhout in his plenary on viral evolution.

Presentations by John Moore and Doug Richman described the development of resistance to the new class of CCR5 inhibitors and their novel mechanism of action. As shown in this slide, binding of CCR5 antagonists results in conformational changes in the CCR5 receptor. In [inaudible] R5 resistant virus combined to the drug bound form as a receptor in addition to the unbound receptor to gain cell

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entry. And furthermore resistant virus [inaudible] as well type virus. [Inaudible] resistance mutations generally appeared in the V3 region of GP120.

There has been concern that treatment of R5 inhibitors will cause co-receptor switch to virus that uses CXCR4 receptor. Indeed, X4 virus does emerge in treated individuals; however, they are selected from the preexisting population indicating the critical importance of a sensitive assay for the detection of minor populations of X4 virus prior to initiating therapy with R5 inhibitors.

Apart from cellular funeral[misspelled?]immunity, recent studies have now demonstrated that specific antiviral mechanisms can be mediated at the intracellular level. Cellular- [AUDIO GAP from 6:19 to 8:30] - shining ridge. The bottom panel, Mirrens are also seeing [inaudible] localizing CD4 positive T-cells in the lumen demonstrating that the virus can interact with target cells that are found in the genital tissue. These studies provide important insights into to how virions penetrate the genital tract and its interaction with target cells.

The [inaudible] immune system recognizes incoming pathogens at mucosal surfaces. An interesting study by Haze and Shattock used a panel of Toll-like receptor ligands to stimulate human cervicovaginal tissue. The data showed that oligonucleotides protect the tissue from infection by HIV,

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which was TLR independent. The activity in the culture supernate [misspelled?] was retained in a greater than 100 philadoton [misspelled?] infection and the secreted with untreated and treated tissue were different by two dimensional gel electrophoresis. These data demonstrate that novel endogenous antiviral factors can be induced in genital tissue and raise the possibility of the use of these factors as mucosal adjuvants.

Given the challenge of developing an effective HIV vaccine, topical microbicides are being pursued as a prevention strategy for the sexual transmission of HIV. Several engines [inaudible] clinical trials. In a late breaking presentation by Eric Arts, a single high dose of vaginally applied Percerantes [misspelled?], which is an R5 blocker, was shown to select for drug resistant [inaudible] in the lacheck model [misspelled?]. The resistant virus was found in the plasma and did not appear to have reduced fitness. The viral inoculum used in this study was not diverse, which raises the question of what will happen with a more diverse inoculum that would be expected in HIV infection. This is the first identification and characterization of resistant virus selected with an anti-HIV microbicide and has major implications to the microbicide field including with agents with different drug resistance profiles should be considered for therapy and prevention.

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Understanding HIV pathogenesis, in other words, how the virus makes HIV-infected individuals sick, is clearly critical in developing strategies to mitigate the effects of HIV. Our current understanding of HIV immunopathogenesis as indicated by presentations at this meeting is crystallized in the diagram. The sequence of events starts with HIV infected, which is pivotal in causing damage to the gut epithelium due to a massive depletion of CD4 positive T-cells early in infection. Physical and immunological damage to the gut leads to leakage of microbial products into the plasma, which in turn results in stimulation of Toll-like receptors on cells in the innate immune system, such as macrophages and dendritic cells. The stimulated cells produce inflammatory cytokines, which results in T-cell activation and expansion, which in turn creates fuel for more virus replication and fibrosis in the lymph node. This occurs in concert with dysfunction of the inductive immune system, which is now being dissected at the molecular level.

So, where are we now with regard to our understanding of the basic biology of the HIV and viral immunopathogenesis? To steal a phrase from Anthony Fauci's opening address, it is fair to say that much has been accomplished, however there is still much more to do. Open questions that still need to be answered, and this is certainly not an exhaustive list, include: Cethamine [misspelled?] activation immodulated to

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reduce viral pathogenesis. Do [inaudible] interference mechanisms provide realistic opportunities for HIV control? Can we exploit host cell resistance factors to reduce antivirals? What are the [inaudible] of effective immunity? Are innate immune mechanisms adequate to control HIV? Can we control viral evolution? Can latent [inaudible] be cleared? And can we produce a vaccine that elicits neutralizing antibodies?

I would like to end this presentation with this final message. Basic research is critical for driving our understanding of how the virus reproduces in the cell, how it interacts with hostile factors, and how it subverts and damages the host's innate and adaptive immune system. Basic research underpins our efforts to translate fundamental research findings into the development of effective drugs, microbicides, and vaccines. And it is terrific that this meeting affords the opportunity for cross-fertilization between pathogenesis, treatment, and prevention areas of HIV research.

Thank you, for your attention.

[Applause]

JOHN KALDOR, Ph.D.: The lead rapporteur for Track B, clinical research treatment and care is Sean Emery, associate professor and head of the therapeutic and vaccine research program at the National Center in HIV Epidemiology and

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Clinical Research, University of New South Wales, Sydney.

Sean has been responsible for developing and leading an extensive network of clinical trial sites, both in Australia and internationally.

[Applause]

SEAN EMERY, B.Sc., Ph.D.: All right, thank you very much. Good Evening. On behalf of my colleagues, Sara Pett [misspelled?], Helen Biaquaga [misspelled?] and Nick Peyton, can I thank the scientific community for organizing two track B late-breaker sessions immediately adjacent to the feedback session. We really enjoyed the rage. We did actually really enjoy the opportunity to serve conference in the way of rapporteurs. Whilst you review our conflicts of interest that we thought was important to share with you, can we also extend our thanks to the ISC to Emily Jacqueline [misspelled?], to Eurous [misspelled?], and to Courtney for their tireless support, and Karen attention in making sure that we were always well looked after.

The coverage of this conference, though surprisingly, was pretty extensive in Track B and in trying to summarize the information presented to you in a reasonably digestible summary conclusion, we adopted essentially a subheading of new drugs and new ways of using the ones we have for better outcomes. We felt particularly strongly that there were important findings applicable to that subheading in the

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resource limited setting, in the context of new drugs, particularly new data from ongoing development programs in the form of new work relating to antiretroviral toxicities and, importantly, the role of strategic clinical research informing clinical practice around the world. And it's on the basis of those subheadings that the rest of the presentation has been constructed.

Two issues predominant in clinical management of HIV disease in resource-limited settings are, of course, tubercular disease and antiretroviral treatment failure including monitoring of treatment responses. Important information relating to the funding policy and infrastructure model from various funding and political agencies was summarized at this conference. We were also provided with critically important information relating to the pharmacokinetic interactions with no nuclear sites and anti-tuberculous drugs from investigators in the U.S. and, more regionally applicable, in Thailand.

Also in the region, investigators in Cambodia provided information that may be important in discerning tuberculosis disease in the form of immune reconstitution disease or incident disease and continuing information relating to the development of treatment protocols for the sequencing of anti-tuberculosis drugs and antiretroviral treatments were also extensively summarized.

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The problem of antiretroviral treatment failure extends to what to do in individuals in which you believe treatment is no longer exerting suppression of virus replication, but it also relates to the complex issue of what method to use for monitoring responses to therapy in individuals who were treated. Investigators from Africa, from Latin America and, again, from Asia, all presented data summarizing their own approaches from a research perspective or from routine clinical practice. And, we were also introduced to the incremental problems of drug resistance in pediatric populations exposed to mother-to-child transmission regimens or in the context of intervention with antiretrovirals in the pediatric setting. All of these are incredibly complex issues.

One striking piece of data derived from the darts enterprise in the form of a neural cohort who were recruited and randomized as a sub-study in the dart protocol, essentially to a direct comparison of abacavir versus neviraprine. It's particularly informative and potentially very provocative in this regard. Investigators were blinded prospectively to CD4+ cell count and plasma viral load outcomes. And, at completion of this particular data search, all of those variables tended to indicate that the surrogate markers favored recipients of neviraprine in terms of treatment success.

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The paradox, when hard clinical end points and outcomes were included in the form of all cause mortality, in the form of various staging systems for WHO, for HIV disease and AIDS, not including tuberculosis, is that all of them appear to stack up very much in favor of abacavir. So there is a readily apparent disconnect between what the surrogate markers might be telling us in clinical practice with what the clinical outcomes in the form of things that actually matter might be indicating.

These data really are extraordinarily controversial and really deserve a great deal of attention. I'm grateful, personally, and this is a personal view that I would now present, for Brian Gazzard's guidance of seeking simple problems for potentially complex solutions. I'm beginning to believe, and felt quite acutely during this particular conference, that we do appear to be moving very divergently in terms of addressing the critical needs of patient care and treatment in countries of the developing world and countries of the developing world. And that actually worries me.

I think we could actually approach this from the perspective of simple solutions for what is quite clearly a complex problem. I think the complexities arise as a consequence of our insistence on restricting use of antiretroviral therapy to late stage disease presentations and the continued use of antiretroviral therapies and monitoring systems that

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we would find completely unacceptable in our own countries. And I think if we were to change those things, we would free up the research and clinical care machinery in a lot of these places to fight some things that actually do matter in terms of these inputs.

[Applause]

Moving swiftly on, Gilda's already summarized a great deal of what was presented from a number of investigators in the form of new drugs for new targets. There were also summary presentations, including critically important pharmacokinetic and pharmacodynamic characterizations for a variety of new drug from existing classes and against new targets. One was particularly of interest to us from Progen, PRO 140, interesting by nature of its chemistry, essentially. This is a CCR5 monoclonal antibody. It is not a small molecule CCR5 inhibitor. It is potentially active against CCR5 resistant HIV and could play a role based on synergistic inhibition of that host cell/virus interaction mediated through that receptor in combination with the small molecule CCR5 inhibitors. The proof of concept for this lead candidate molecule - the pointer isn't working, excuse me - clearly showing a nice graded dose response over a period of 10-day exposure to mono-therapy with that agent. This is very promising. We look forward to further work with this class of agent and possibly also this particular lead material.

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Impressive work continues to arise from the ongoing development program for raltegravir, these data presented by Monty Markowitz from the 004 protocol describing the comparison of a group of individuals, around 160, who received raltegravir at one of four dose levels, compared to a group of individuals who received efavirenz on a common nucleoside backbone, all indicating potent and sustained suppression for raltegravir recipients over a period of 48 weeks. From what we have learned at this meeting, over that period the drug is extremely well tolerated and safe. We're thankful to both Marty and others for introducing us to the concept of the evolutionary pathway associated with the development of reduced sensitivity to this class of agents. And further work is clearly required to define that pathway.

Introduction of new classes of agents also provide an important opportunity to examine pathogenesis. And Joe Murray presented data at this conference in which investigators looked at the inflection point from Phase I to Phase II in the DK curve, in this region - I'm sorry, it's not terribly discernable here - for the group of raltegravir recipients compared with those who received efavirenz. There is clearly something really quite substantially going on there. And the [inaudible] of equilibrium between host and pathogen at that inflection point, under the influence of an integrate inhibitor

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could be quite meaningful, both from the pathogenesis mechanism and potentially also from a clinical management perspective.

Small molecule inhibitors I've all grouped together. That's probably not terribly smart, but I do believe that they don't share a great deal of class-wide characteristics. Data were presented at this meeting from maraviroc, vicriviroc and INCB that [inaudible] 9471. All appear to be biologically active in terms of the capacity to suppress viral replication in reasonably potent ways. They all appear to be safe and well tolerated. I felt that there is a question mark to be asked about the incidence of cancer in recipients of vicriviroc. I'm grateful to John Moore [misspelled?] and Doug Richman [misspelled?] for some really elegant presentations introducing some of the complexities of addressing the issue of tropism, an assessment of drug resistance when considering the place of these drugs potentially in clinical management.

And then today we were shown the completed treatment naïve protocol for maraviroc versus efavirenz on a common backbone of Combivir, clearly establishing essentially equivalence based on 48-week responses on an assay of less than 400 copies per mL. But perhaps of some concern, and indication through this data set that the potency of maraviroc might be called into question for more sensitive assays for virus replication.

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Congratulations to Teva Tech for the very successful completion of a number of studies comparing etravirine and ritonavir-boosted darunavir, and also to their investigators. Flippantly I will also congratulate them for more or less completely filling an entire issue of the *Lancet*.

I don't intend to introduce any more data because they've been well canvassed and quite rightly so. They are terrific new options, etravirine providing a valuable, new, safe non-nucleoside option in a salvage setting. And I believe ritonavir-boosted darunavir a credible option when individuals are considering the use of ritonavir-boosted PIs in the treatment experience setting.

Toxicities: It is, of course, entirely appropriate that the story of abacavir hypersensitivity concludes in Australia at phenomenally data rich sessions. We've had indications of the underlying immunologic mechanism resulting in hypersensitivity, validation of a rapid screening test based on flow cytometry, further information to describe the use of skin patch testing in confirmatory situations. And of critical importance, completion and presentation of the Predict study that I've summarized on one slide in this instance. It's very clear that prospective use of HLAB57 screening really effectively removes all, for all intents and purposes, clinically presumed hypersensitivity reactions to abacavir.

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And it certainly completely removes all of it on the basis of immunologically confirmed events.

Many sites around the world have moved from an opinion basis to the use of abacavir hypersensitivity testing based on HLAB57. It's critically important that that opinion based medicine is ultimately confirmed by these definitive pieces of work. And the investigators are to be congratulated. I'm pretty sure that the folks at GlaxoSmithKline are incredibly smart and would have considered this as a potential outcome. And I'm looking forward to GlaxoSmithKline playing a role, at least of some sort, of how we roll out the necessary resources to provide testing for this particular important toxicity. Perhaps, based on the presentation from Hasi Katel [misspelled?], that might not be necessary.

A direct comparison of Kivexa with Truvada in virologically controlled patients on existing regimens of two nucleosides plus a third agent, a comparison for the primary end point, established that the regimens were not non-inferior and the secondary end point indicated - with considerable caution I must add - that there was some indication of superiority for Truvada over Kivexa. This work warrants further investigation. And I'm aware of other trials that will appeal to that particular objective.

Moving swiftly on, many people have been aware that there's an undercurrent of interest in the question of when to

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start antiretroviral therapy. Pediatricians involved in the Share study and their collaborators from around the world, with support through the CIPRA program, are to be congratulated on providing some really quite robust and definitive data based on a randomized trial in 252 individuals, age 6 to 12 weeks, with more than 25-percent CD4 cell percentage had entry into the study. Randomized into three arms, two immediate, one deferred, following interim review through an independent data safety monitoring board, recommendations have now been implemented to cease the deferred arm because of an overwhelmingly strong signal of poor outcomes based on mortality in the deferred arm. Really strong studies, strategic in nature by design, properly conducted and having an immediate impact upon treatment guidelines based on strong end points that affect practice, policy and further research.

The question is somewhat more vexed in the adult/adolescent setting. We have had a number of presentations that provide a foundation for the immunologic basis of the trial of early interventions with antiretroviral therapies from Letterman [misspelled?], Shacker [misspelled?], and Levi [misspelled?], extensive cohort data from Newton, investigators in Brazil and two from the U.S., examining a range of cardiovascular outcomes at the population level and also in other settings. A clinical picture from Brian Gazzard and Fred Gordin and some data from myself in collaboration with

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others, and a strong public health compulsion to examine the question of early treatment in adults with HIV infection from Julio Moltagne [misspelled?].

Moving swiftly on, D-dimer is a marker of [inaudible] degradation. It's not been looked at extensively. Why on earth would it have been in HIV disease? Information from the SMART trial really indicating that there appears to be some sort of aberrant immune response that's generating a whole range of biomarkers that are linked to really poor clinical outcomes, particularly in early HIV disease. These data are absolutely fascinating and deserve to be tested in a properly designed randomized clinical trial of early HIV therapy.

In summary, we welcome all of the developments on all of the fronts that have been covered by Track B. Surprising to see there was no oncology content. I've always been enormously impressed by the passion, the commitment, some of the guile and all of the devotion that everybody exhibits during these meetings. My plea to you all is: Maintain the rage, but remember that the enemy is the virus. On behalf of my group, thanks very much.

[Applause]

CRAIG MCCLURE: Track C, Biomedical Prevention, was added to the program of the third conference of this series in Rio two years ago as a pilot, acknowledging the dramatic expansion of research in this area. For this conference in

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Sydney, biomedical prevention has been added formally and permanently to the program, and in fact to the title of the conference, not least because of the dramatic expansion of research in the area but also because of the commitment of the IAS to a much more integrated approach to treatment and prevention in HIV disease.

The lead rapporteur for Track C at this conference was Dr. Lisa Maher, the head of the Viral Hepatitis Epidemiology and Prevention Program and the National Center in HIV Epidemiology and Clinical Research at the University of New South Wales, Sydney. Dr. Maher is a medical anthropologist with extensive experience in research, particularly with injecting drug users communities and other communities most at risk of HIV. Dr. Maher?

[Applause]

LISA MAHER, M.A., Ph.D.: Thanks. I'd like to start by acknowledging AS for the opportunity and also my co-rapporteurs, Rebecca Guy [misspelled?] from Burnett Institute, Iona Milwood [misspelled?] from the National Center in HIV Epidemiology and Clinical Research, and Nick Walsh [misspelled?] from Monash University.

This is the interesting slide, which we thought was worth putting up, because it covered some of the bases I hope to cover in this rapporteur session, even though the data are a little bit old. But you can see coverage still remains an

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issue, even with more recent data, but particularly very low rates of coverage of harm reduction intervention of injection drug users globally.

There were quite a few sessions on voluntary testing and counseling and testing, in particular two different types of testing: provider-initiated testing and voluntary counseling and testing. A number of presentations covered provider initiated testing. And particularly coming from the U.S., but also a presentation from Botswana and I guess ongoing concerns raised about human rights issues in relation to provider initiated testing in some settings.

The scale up of voluntary counseling and testing: some data presented from a range of different settings, particularly in Uganda where about 250,000 people were screened in a two-year period, and interesting report of a trial of streamlined counseling in Veterans Affairs clinics in the U.S. that compared - actually, I've got a slide on that, so - yeah, compared the no screening with no screening and rapid testing, and showed a significant increase in the uptake of results, particularly with the addition of the rapid testing.

One presentation on STI treatment, which was a randomized control trial in northern Tanzania: Vacyclovir twice a day, 26-percent of the people withdrew from taking the tablets, 79-percent due to pregnancy. There was no impact on

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HIV incidence. But there is more data to come with two large RCTs currently underway.

In relation to injecting drug use, we're reminded again that injecting drug use accounts for about 10-percent of the global burden of HIV infection. It's the main exposure in Eastern Europe and parts of Asia. And something I will come back to in a concluding slide was the need for evidence based prevention packages. And we have fairly good evidence in relation to injecting drug use now of the efficacy and effectiveness of needle and syringe programs, [inaudible] substitution treatment, risk reduction counseling and some evidence in support of the efficacy of supervised injecting facilities.

We're presented with more evidence of feasibility and effectiveness of OST and in particular some interesting data from the Ukraine. And an interesting presentation from Canada: strong associations emerging between decentralization, increased access, and removal of restriction from the quantity of equipment and risk reduction behaviors, both borrowing and lending of needles and syringes. And a very powerful presentation by Guaran Yari [misspelled?] on stigma discrimination and human rights violations, and reminding us that both problems are still pressing issues facing IDUs globally.

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Prevention of mother-to-child transmission: Two studies presented looking at heart [misspelled?] and breast feeding, both showing less than 1-percent of infants infected. These results suggest - and obviously we're not a team of clinicians, but it's probably safe to breast feed if women are getting treatment and they're having good viral suppression. And this is important to consider, given the considerable morbidity and mortalities associated with formula feeding in different settings, particularly resource-poor settings where the costs, which may be more expensive than heart and there are often hygiene issues associated with formula feeding.

There are a number of ongoing and recently completed large scale HIV prevention trials, looking at prep, microbicides, HSV2 suppression, cervical barriers and female condoms. Nearly all are effectiveness studies with very few Phase II studies included. We had another great slide from Willard Cates [misspelled?] on the prevention trials pipeline. You can see a range of things that are in progress over the next few years.

We also had some results, some [inaudible] HIV prevention, and particular results from nearer Phase III randomized control trial in South Africa and Zimbabwe, where they found no additional benefits in the intervention arm, high rates of retention and only 5-percent of those women lost to follow up, 73-percent adherence, and an interesting sub-study

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of male partners, where 95-percent indicated support but only 4-percent actually attended the clinic. In the DMS study in Zimbabwe, they found that condom use was strongly associated with adherence to the study product. And data presented on the Phase III trial of cellular sulfate reported that Conrad was halted early due to increased HIV incidence. And the FHI trial was stopped as a precaution, I guess as a consequence of the Conrad trial being halted. We tried to - I guess tempered up some optimism is probably the best way to explain or summarize that perspective of these results.

HIV vaccines: And we had a bit of expert advice into this. Ongoing Phase IIB vaccine studies expected to elicit CTL responses only, but they may have potential benefits, particularly public health benefits, even if they do not prevent primary infection. And some of those secondary end points might include slower rates of HIV progression, reduced potential for HIV transmission, increased durability of the T cell response, and extending or delaying the time to ART initiation. It was pointed out that still little is known of the correlates of immunity. And we know very little about the acceptability of different types of vaccine candidates with different mechanisms in different sub-populations.

Male circumcision: We had a very interesting plenary, which reviewed the results from three randomized control trials in heterosexual males, and showed a very strong protective

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effect. Some interesting data on cost per HIV infection [inaudible] was presented. And I guess most of the debate, both in the sessions and in the hallways, is around the kind of implementation issues and the issues involved in whether you go forward, and if you do go forward in putting that evidence into practice. We also had data presented from two observational studies in men who have sex with men, which showed no association between circumcision and HIV infection.

Social and behavioral: We were reminded of that fact, in a couple of sessions, actually, that prevention is prevention, whether it's biomedical, social, behavioral or other kinds of structural prevention, whatever you want to call it. The need for having a suite of evidence based interventions employed concurrently: again, reminded of the interdependence of social and biomedical interventions, and to keep reminding ourselves that efficacy does not necessarily translate to effectiveness in real world conditions, and the need to integrate social science research and social science arms into prevention trials.

Just talk quickly about some of the challenges that were discussed over the conference. Obviously randomized control trials are necessary but not always sufficient policy. We need to think about the capacity of health care systems, particularly in resource poor settings. More work to be done around acceptability in relation to both biomedical prevention

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and social forms of prevention. We heard about the need and ongoing need, which we're constantly reminded of at this and other conferences, for early and effective engagement with communities, the need to understand local issues from the contest, from the perspective trial participants and end point consumers, to have a better understanding of ethical issues and issues affecting adherence and adherence monitoring and cost and sustainability.

And we also had some interesting data presented on the cost of HIV prevention trials. And you can see on this slide from Willard Cates, microbicide trials ranging from \$5 million to \$67 million. But interesting data is the cost per end point, which range up to \$425,000, I think, U.S. dollars. A bit of a different story for male circumcision trials, were I think the quote was that they represented the best buy in terms of the cost per end point.

Considerations: existing interventions. I think we're reminded of the fact that we sometimes forget - I guess it's the lure of technology and having new and sexy things to be able to give or offer people, but condoms and needle and syringe programs actually work. The new interventions will have, if anything, partial efficacy. They'll need to be considered as part of prevention packages. And there's a real need to think about our prevention packages, to think about standardizing them, to make sure that they're evidence based so

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that people, particularly when they're setting up trials, aren't cherry picking and just selecting the parts or the interventions that they like, excluding the ones that we may not like but we have good evidence of effectiveness.

We also need to think about prevention in terms of the bigger picture. Yeah, just I guess all those kinds of things that we think are not our job, that they're the job of somebody else, but to do lower form to advocate for legislative change, the community and peer involvement, for access to health care, poverty reduction and microfinance program.

And for conclusions, just to recap, we heard, yeah, in relation to male circumcision, strong evidence of efficacy in heterosexual men, tempered optimism the data suggesting the data suggesting the relation to microbicide candidates, very much a wait and see in relation to HIV vaccines. I think some of the most important and interesting data presented at this conference, certainly from our [inaudible] perspective, were around the lessons that we've learned in some of the prevention trials, the biomedical prevention trials that have been conducted to date.

Again, the need for early and effective engagement with communities, and the data on the process and the methods, the sort of social and acceptability research, are just as important as the primary end points. And we saw some important presentations on willingness to participate, about

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discrepancies between people who indicate willingness to participate, but then when it comes to actually signing up and taking part in a trial, that some groups are perhaps more likely to have willingness to participate in studies than others. Issues around acceptability, recruitment and retention, but a lot more research and thinking needed there. There's a need to take social sciences and social sciences seriously. And I guess, perhaps something of an artificial separation between biomedical and social and behavioral prevention.

And I'll leave you with the thought that prevention probably is just prevention. Thank you.

[Applause]

JOHN KALDOR, Ph.D.: Thank you, Lisa. The last presentation in this session is community statement, and it's a pleasure to introduce John Daye. John's been working in community advocacy for over 10 years and played a number of very significant roles, including his membership in the International Treatment Preparedness Coalition and a number of national roles and state roles in Australia. He's also served as a member of our research centers clinical trials working groups over a number of years, and has been a crucial partner in helping us decide a number of issues in relation to trial development.

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And in regard to this conference, John has represented the community advisory group that's worked with the conference organizing committee providing community input over the last period of preparing the conference. So it's a pleasure to introduce John.

[Applause]

JOHN DAYE: I'm honored to present this closing statement on behalf of the community advisory group, and grateful for all the input of the community members who are actually attending this 4th International AIDS Society Conference here in Sydney.

We've heard a lot about new drugs, but with the introduction of new drugs, and some especially in new classes, improved efficacy, toxicity and resistance profiles, it's become evident that we really need studies to give us a clear understanding of what is the optimal time to commence treatment through new randomized clinical trials. If the paradigm around when to begin treatment is shifting, we need to insure it's based on sound evidence.

Significant improvements for people who are highly treatment experienced is very welcome at this conference. With access to new drugs and a rich pipeline, it should now be possible for most people to reach and sustain undetectable viral load. However, with these new drugs, it will be important to understand their place in treatment for those

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initiating therapy as well. We still have a lot more to learn about when and where to use these new compounds.

We strongly support the protest of the Thai activists against Abbott's hard stance on supplying Alluvia to Thailand, because it reminds us that no matter how good our research is on new therapies, it will only be successful if the treatments can be accessed globally at affordable prices.

[Applause]

Please sign the petition on the way out and sign online.

One of the successes of this conference is that it has paved the way through an opportunity for much needed dialogue between community and industry. This dialogue is crucial but must continue until people have access to medicines, regardless of where they live. This will become an even greater challenge if antiretroviral guidelines are revised and treatment is recommended to start earlier.

We've been reminded at this conference that for every person who is put on treatment, there are six people who become infected. And the fear is growing that we cannot treat our way out of this epidemic. We hear time and time again in the prevention research track about the importance of community involvement in developing, implementing, monitoring and evaluating prevention research. We still have to move from rhetoric to reality. As Mara Meade [misspelled?] said in her

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opening talk, we need to put into action the principle of talk with us, not about us. This is particular important with regard to the issue of more women in research and more research on women, an issue that was raised by the Anthia [misspelled?] Coalition and echoed by community members of both sexes.

With all the excitement around circumcision, we cannot forget that we have existing technologies and harm reduction interventions such as needle exchange that have been shown to be as good if not better, and yet we have not even implemented them in many settings for lack of political will and policies driven by ideology rather than evidence. The time for pilot studies has really passed, and we need to implement them now.

[Applause]

We hear from Dr. Kevin De Cock of the World Health Organization that the need for provider-initiated opt-out counseling and testing trumps the critical issue of ongoing stigma and discrimination. This is not only naïve, it does not take into account that in countries where human rights are not protected, this will potentially and inadvertently put people's lives at risk.

[Applause]

This is why we do not understand why biomedical prevention research is presented in a vacuum at this conference. We need sociobehavioral research presented as well

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in order to give us the full picture. We simply cannot separate prevention technologies from human behaviors.

The Sydney Declaration calls for dedicated funding for research. We are now prepared to support the Declaration with additional input that will be communicated to you by Pedro Cahn in a few moments.

This has, by all accounts, been a rewarding conference for community delegates. We can be very proud of the benchmarks we have set for community participation and engagement in the conference. In particular, I want to acknowledge the contribution of my fellow members of the Community Advisory Group, the Activist Liaison Program, the Positive Lounge, the Local Engagement Tours and the Community Forum, which allowed local community members to hear issues here from the conference.

Thanks to the IAS team and to all of our volunteers for their support. And we very much hope that we have set the bar high for future conferences. Thank you.

[Applause]

CRAIG MCCLURE: I'd just like to note before we leave that all of the rapporteur reports will be loaded up on the website tonight, and a report summary of the scientific and other programmatic highlights of the conference will be available on the Web site within the next two weeks.

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This has been a rich and intense program of cutting edge research across the three tracks. And the work of the volunteer lead rapporteurs and their teams, as well as John Daye and the other community advocate supporters on his team has been intense, enormous and extensive. I think we all owe them a huge round of applause for their volunteer support.

[Applause]

We'll be going straight into the closing session now, so if you'd like to remain seated, we'll get going in just a moment.

DAVID COOPER, M.D., D.Sc.: Well, groups, it's been an amazing journey, 6,000 of my colleagues and friends together in my home city. What a party. But like all great parties, it's over in a flash. The best part of this party is that there's no long plane ride home. [Laughter] Thank you, and thank you to the delegates, friends and organizers. I hope you've had a truly great meeting as I have.

It's my happy duty as local co-chair in Sydney to hand the baton to my colleague, Jerry Cavardia [misspelled?], and congratulate him on the selection of Cape Town for IAS 2009. Long live the southern hemisphere. [Laughter] Jerry, as many of you will know, is chair of the amazing Durbin meeting in 2000, and also the first South African AIDS conference, so he's extremely well equipped to give you as splendid a meeting as you've had here this week. Just a piece of advice, Jerry:

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Don't give Brian Gazzard or anyone else photos of you when you were young. They may turn up in most embarrassing ways.

[Laughter] Cape Town, of course, will remind us of the seminal meeting in Durbin, which was so important, so crucial, and so successful in focusing international attention on HIV/AIDS in the developing world.

Much the same intention lies behind the Sydney Declaration, of which I'm very proud to be the first signatory. I urge you all to add your names to the growing list, literally to stand up and be counted amongst those of us who believe that only good science and good research can insure that the treatment rollout is done with the greatest possible benefit in the most vulnerable populations. Please go to the Web site. Already almost 1,600 have supported our call for 10-percent funding amounts in addition to be allocated to research. Notwithstanding, we need to keep the momentum going and we need to bring the declaration to fruition.

I'd like to thank every one of the 3,000 abstract authors who submitted their work for IAS 2007. And I congratulate the almost 1,000 whose work was presented. The scientific program at this meeting has highlighted the enormous potential of new drugs and new classes of drugs, of new avenues of biomedical prevention, and of course the need to constantly move forward.

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I'd like to thank many, many people. And I've certainly done that personally. But I'd certainly like to thank IAS, Anashem [misspelled?] and all their officers and workers for the amazing job they did in getting this conference together. I'd like to thank the sponsors, both the public and private sector. And I'd really like to especially thank, and please give a round of applause to the volunteers and also to the AV people. I think the presentations were just absolutely flawless at the meeting.

[Applause]

If there's one person I personally would like to single out for thanks in this setting, it would be Emily Blitz [misspelled?]. I've worked with Emily for many years [applause] in the program committees of this meeting. And as usual, she's done an amazing job, if not more amazing than ever before. Thank you, Emily.

So, we must never lose sight, either scientifically or personally, of the people who need our work to succeed. I look forward to seeing you all in Cape Town. Have a great rest of your time in Australia, in this wonderful country, or in Sydney or wherever you're going here. And please have a very safe trip home. Thank you.

[Applause]

JERRY CAVARDIA: There's supposed to be a logo of Cape Town coming up. You'll see that it indicates those curlicues

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and waves, suggesting that when the first Portuguese and Dutch colonists came, they called it the Cape of Storms, and that's what it's supposed to reflect. But it's much peaceful now.

And I don't want to keep you one second longer from enjoying the delights of this most loveliest of cities, one of the really lovely cities, not only in this part of the world but in any part of the world. And it struck me when I looked at all the previous pathogenesis conferences, they've either by coincidence or design or contingency chosen the loveliest places to be on this earth. Really, they've been in Buenos Aires, they've been in Paris, they've been in Rio. Now they've been in Sydney, and then they're coming to Cape Town.

So all I want to say to you is there are one or two reasons why I'm here to speak to you to ask you to come to Cape Town, one of which is, without doubt, the Cape, like all these other cities I've named, is really a beautiful city. It's one of the most beautiful cities in the world. It contains not just natural beauty, but it's really the mother city of Africa. It's the first place where European colonists came in the 15th century. It's a place where different cultures have come there. People come through the Indian Ocean from Indonesia and Malaysia. There have been European and British colonists come from the Atlantic Ocean. And the land mass itself introduces the African culture and its people to one city and one place.

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So that's one reason. But there are two other reasons. And one is to remind you that when some of you came to the Durbin conference, it changed our lives - that means South Africans' lives, Africans' lives - and indeed the world's approach to HIV fundamentally. And I think that's what I'm asking you now. What you did when you came in 2000, with the help of the International AIDS Society, is that you transformed a huge debate.

And I remember, I think it was David Ho [misspelled?] in his first slide, he showed the HIV virus and he said, "This is the virus that causes AIDS." And he got a standing ovation, for the reasons which you might have forgotten. And the reasons were, there was this amazing, almost antediluvian debate in my country about what causes AIDS. And that one slide, and that one - the presence of all of you there, and the Durbin Declaration, which was signed by 5,000 scientists, if I remember, many of them Nobel laureates, really changed the debate about what science means and what sources of information mean, so that now, some years later, almost about eight or nine years later, the country has changed completely. The country has changed completely, so that we have a first-class national plan, we've got a transformation, what we can do and what we are doing, and we are gradually building the elements of a world class program in a developing country against HIV/AIDS.

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So what I'm asking you to do is to repeat that performance, because there's much else that has happened. I can't go into all the other benefits that happened. We had a complete transformation in the country, too. But we're now on the - by the time you come, we will have a new election and new government and we will have to apply what we have learned here about pathogenesis, prevention and treatment, in the most scientifically rigorous manner to the problems of developing countries.

And I'm not just talking about scaling up. Scaling up just means adding more of the same. It's difficult, and I understand, but we need your help, so that we together can find the real synthesis between these basic and clinical and other sciences with the propagation of programs, with the attempts to confront this epidemic and drive it back in the worst effected regions of the world. So that's why I think you should come. So please do. Thank you very much.

[Applause]

[Video playing]

[Applause]

PEDRO CAHN, M.D., Ph.D.: Well, thank you, Jerry, for this marvelous film. It was a surprise for all of us, including myself.

I would like to acknowledge that we have in the audience the Minister of Health of the province of Western

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Cape, Dr. Wes [misspelled?]. Very welcome for having joined us in this closing session.

So thank you for remaining for the closing session of the 4th International Conference on HIV Pathogenesis, Treatment and Prevention. It has been an intense three days. No doubt you have attended many sessions and have been inundated with lots of new information, in addition to making new contacts and formed, I hope, new collaborations for your work in the future. I am sure you are all tired and thinking of home, so I will keep my remarks very brief.

First, I want to say that the International Society and our local partner, the Australasian Society for HIV Medicine, are thrilled at the success of this meeting. Over 6,000 participants, including 5,000 delegates, plus media exhibitors and accompanying persons from every corner of the globe have congregated here in Sydney this week.

Second, I want to make the point, so eloquently outlines by World Bank AIDS Director Debrework Zwedie on Monday's plenary, that we will never achieve and sustain universal access to treatment and prevention if we don't build strong healthy [inaudible] throughout the world. This can only be done if countries expand their health workforce including their research capacity and infrastructure. And, as Global Fund Director Michel Kazatchkine pointed out, health is not a

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consequence but an essential component of development. Again, poverty and development are in the middle of this issue.

This leads inevitably to my third point, the Sydney Declaration. I am grateful to all my colleagues, including community members, who often [inaudible] the Sydney Declaration and have taken the time to look at it carefully with the decision to further strengthen its message. The purpose of the Sydney Declaration is to increase by not less than 10-percent all resources dedicated to HIV research for the purpose of optimizing our intervention and health outcomes. This includes monitoring and evaluation to continually improve performance, operational and cost effectiveness research, as well as the basic clinical and social science needed to further our understanding of the epidemic, its impact and our response.

It is important to clarify that when we talk about expanding and integrating research into oral HIV programming in countries, we do not mean increasing research at the expense of treatment and prevention programming.

[Applause]

Rather, we are saying that universal access to HIV treatment, care and prevention cannot be achieved and sustained without increasing our research investments and integrating research as an integral part of our efforts to build the health system that can insure our commitments can be realized. And of course that means ethical research that operates in accordance

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with fundamental human rights principles and has people living with HIV and the most affected communities at the center of the process.

As a special remark, I would like also to highlight our relief that after eight long years, the Bulgarian and Palestinian health workers, confronting a death sentence, have finally been released from Libyan detention and returned home to Bulgaria yesterday.

[Applause]

This is a great victory for all of us committed with human rights and health care workers rights in particular.

Finally, I want to encourage the delegates to submit abstracts for the 17th International AIDS Conference to be held in Mexico City. Abstract reception opens in November, 2007, so please watch the IAS and AIDS [inaudible] Web sites for details.

It also gives me great pleasure to announce the 5th International Conference on HIV Pathogenesis, Treatment and Prevention in Cape Town, South Africa. I am delighted that we are once again bringing an IAS conference back to Africa and to one of the countries most affected by this pandemic.

Before I read my last paragraph, I would like to ask some people to come to the podium: Craig McClure and his staff, Max, Emily and every single member of the staff that is here in the room, as well as Lavenia, groups and [inaudible] staff.

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These people were absolutely instrumental for making this conference a great success. They have been working in the last three years for this conference. Please join me here.

[Applause]

I think you deserve a round of applause. Lavenia and people from [inaudible], please come also to the podium.

[Applause]

I want to again say to my co-chair, Dr. David Cooper, the many committee members and other volunteers, the sponsors, staff, for working tirelessly to make this conference such a huge success. I hope you all had a great conference. I wish you safe travels. See you in Cape Town. Thank you very much.

[Applause]

[END RECORDING]