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Rapporteur Session: Prevention Science

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Overview 1

Good morning. Track D included presentations on the prevention of HIV, both behavioral and biomedical, and what I plan to review briefly this morning is shown on this slide.

Slide 1. Tack D Overview. Behavioral, social and policy prevention

- Behavioral, social and policy prevention
  - Behavioral intervention trials
  - Counseling and testing
  - Harm reduction
- Biomedical prevention
  - Sexually transmitted infections (STI) and HIV
  - Vaginal microbicides
  - Antiretrovirals and HIV transmission
    - Prevention of mother-to-child transmission (MTCT)
    - Pre-and post-exposure prophylaxis
  - Vaccines

Behavioral Intervention Studies

In the area of behavioral prevention there were many well conducted randomized controlled trials and community intervention trials, both large and small, and many other smaller evaluations reported. These reports have added to our already solid base of evidence for the efficacy and effectiveness of interventions to prevent the transmission of HIV on which our control of the epidemic is so deeply dependent.

Prevention for adolescents

Let me start this overview with youth. While the evidence base for abstinence-based education may be lacking[1], four well designed and skillfully conducted randomized controlled trials from Britain[2], Spain[3], Thailand and Mexico[4] and the Philippines[5] have increased the evidence that educational programs for adolescents can decrease risky sexual behavior. For instance, a binational trial of school-based educational programs in Mexico and Thailand that incorporated best practices from previously evaluated models and found a cleear association with increased condom use.

Slide 2. Behavioral Interventions Adolescents - RCTs

- Systematic review of sexuality education trials - minimal evidence of effect
  - Wright-De Aguera (TuPeD5041)
- School-based RCTs showed improvements in knowledge and decreased sexual risk
  - Kay, Britain (WeDOr1274)
  - Steward, Thailand and Mexico (WeOrD1275)
  - Diez, Spain (WeOrD1296)
  - De los Reyes, Philippines (TuPeD5006)

Behavioral interventions. Heterosexual adults - RCTs

Heterosexual transmission of HIV is rampant in the developing world and is the target of multiple bio-

Slide 3. Behavioral interventions Heterosexual adults - RCTs

- Interventions in the developing world
  - Microfinance scheme for young women in South Africa - Hargreaves (TuPpD2066)
  - Communications channels – Low-Beer (WePeD6385)
- Interventions in the industrialized world
  - 6-session counseling intervention for high-risk heterosexual women in New York, no difference between couples v. woman-only counseling - El-Bassel (TuOrD1238)

medical intervention trials. On the behavioral intervention front, however, reports from trials from the developing world were few. One exception was the IMAGE study, a fascinating community intervention trial that is examining a microcredit financing scheme for young women and their households in rural South Africa and has HIV and unwanted pregnancy endpoints[6]. This trial is at the end of its first year, and I will be eagerly awaiting its results in Bangkok.

Behavioral trends among men who have sex with men

There were multiple reports of riskier sexual behavior among men who have sex with men in the developed world[9]. Certain sexual practices have evolved, which although perceived to be safe, could result in HIV transmission and are not usually captured by sexual history questionnaires. These include "dipping"[10] or delaying use of condoms in early anal intercourse[11]. This practice was associated with recent seroconversion and was not perceived to be risky by gay men in Ontario.

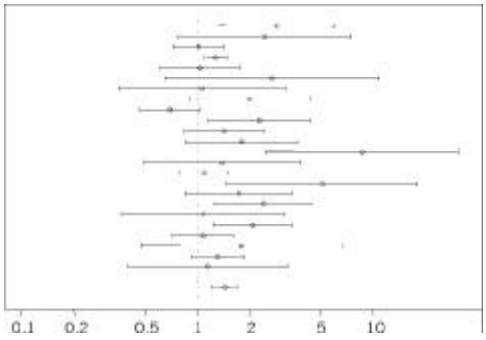
Slide 4. Behavioral trends among men who have sex with men

- Increasing rates of unsafe sex
  - van de Ven, Amsterdam (ThOrD1491)
- High-risk sexual practices
  - Dipping - Hoff (TuOrD1196)
  - Delayed condom use associated with sero-conversion and poor understanding of risk of infectiousness of pre-ejaculate - Calzavaza (TuOrD1197)

Best prevention program practices

An especially powerful tool for compiling best evidence, systematic reviews, was used in several presentations. Darbes and colleagues systematically reviewed randomized controlled behavioral intervention trials conducted among African-American populations in the United States and found that interventions that were gender- and culture-specific were more frequently associated with decreases in risky sexual behavior than those that were not[21].

Slide 5. Best prevention practices Systematic reviews of behavioral intervention trials in African Americans Estimates of Effect Size by Study



Darbes (WeOrD1350)
Odds Ratio & 95% CI (log scale)

Counseling and testing 1

Voluntary counseling and testing or VCT is an important tool in HIV prevention and one that needs to be scaled up drastically as treatment is extended throughout developing and transitional countries. What happens when VCT is made widely available was evident in a paper from Thailand by Rumakon, which showed that after the introduction of widespread VCT the time from HIV infection to diagnosis fell 2.55 years[24].

Nonetheless, problems remain. Young men are substantially less likely to seek VCT than women in Thailand and in Uganda[25]; stigma, lack of treatment and social isolation remain obstacles to seeking VCT in South Africa[26].

Counseling and testing

- Introduction of VCT associated with decreased time to diagnosis in rural Thailand by 2.55 years - Rumakon (MoOrD1017)
- Young men less likely to seek testing than women in Thailand and Uganda - Juma (MoOrD1023)
- Stigma, lack of treatment, social isolation significant barriers in South Africa - van Dyk (MoOrD1020)

Counseling and testing 2

And in the developed world there are substantial missed opportunities for VCT among antenatal pa-

tients[27], high rates of failing to return for results[28] and substantial anxiety about getting tested for fear of results[29]. Failing to return for testing results is especially problematic[30], and, while rapid testing can dramatically increase the proportion who receive results, it is not necessarily associated with long-term decreases in risk behavior, at least in STI patients as shown in the RESPECT-2 trial[31,32].

Slide 7. Counseling and testing

- Substantial missed opportunities for VCT
  - Pregnant women in California - Montgomery (ThOrD1399)
  - MSM in Scotland - Flowers (ThOrD1201)
- Failing to return for test results
  - STI clinic patients in U.S. - Lansky (ThOrD1399)
  - RESPECT-2 trial - no long-term benefit of rapid testing - Metcalf (MoOrD1018, MoOrD1019)

Improving delivery of VCT

Several other studies highlighted ways to improve VCT services. Kalibala and colleagues described a wonderfully successful intervention to strengthen the integration of VCT, family planning, tuberculosis and STI services in Uganda[33]. Other papers described new ways to expand VCT, such as in residential drug treatment programs[34], at home for TB patients[35], in mobile vans[36] and via the Internet[37].

Slide 8. Improving delivery of VCT

- Integration with STI, TB and family planning services in Uganda
  - Kalibala (MoOrD1022)
- Expanding venues for VCT
  - Residential drug treatment - Strauss (MoOrD1400)
  - Homes of TB patients in Zambia - Ayles (ThOrD1402)
  - Mobile vans in California - Rasmussen (ThOrD1401)

NIGHT outreach program

The mobile van study from California provided especially impressive results and may be a model that can be replicated elsewhere. Over a four-year period they tested over 100,000 individuals and found 1,174 positives; they were far more likely to counsel and test groups historically underserved by VCT, including drug users and sex workers.

Slide 9. Mobile Vans

The NIGHT Program funds the operation of 7 large mobile vans that are used in urban areas...

As well as 12 smaller vans that are used throughout the rest of California. 104,850 tested and 1,174 HIV infections diagnosed

Rasmussen (ThOrD1401)

California Department of Health Services, Office of AIDS
University of California, Office of the President, Universitywide AIDS Research Program

Harm reduction

Harm reduction was examined in several studies presented at this conference. That needle exchange is an effective intervention for decreasing parenteral transmission among drug users has been clearly established but the nuances somewhat less so. Sherman and colleagues from Baltimore found that injection drug users who attended needle exchanges frequently were promoting safe injection practices among less frequent attendees[38]. Of interest for future programs, these frequent attendees may be able to act as effective change agents for drug users that stay away from needle exchange. Shoptaw and colleagues described a randomized controlled trial of an innovative incentives and counseling intervention for gay male amphethamine users in Los Angeles, which

found strong effects on both abstinence from drugs and sexual risk taking[40].

Slide 10. Harm reduction

- High-volume exchangers may be way to reach IDUs who stay away from needle exchange in Baltimore - Sherman (MoOrD1061)
- Needle exchange must be more widespread and for the long term in Belarus - Vickerman (MoOrD1062)
- Innovative incentives and counseling for methamphetamine-using MSM in Los Angeles - Shoptaw (TuOrD1199)

Biomedical Intervention Studies

I'll move on now to biomedical interventions.

Mwanza, Rakai and Masaka

In 1995 the landmark Mwanza study found that syndromic treatment of STIs and the provision of an STI treatment infrastructure in the rural Mwanza area of northern Tanzania were associated with a decrease in HIV incidence. This promising finding was seemingly contradicted a few years later by a study of periodic mass STI treatment in the Rakai district of Uganda. A third study, conducted in Masaka, Uganda, found no effect for syndromic STI treatment on HIV incidence. A Track D symposium examined these three trials and the reasons for their different findings in depth.

Slide 11. HIV and STIs Mwanza, Rakai and Masaka studies: redux

Mwanza, Rakai and Masaka. Sexual behavior

The basic consensus that emerged, based on reanalysis of the data from the trials[45-47], was that the study population in Mwanza had higher risk behavior at baseline, as shown in this slide in red.

Slide 12. Mwanza, Rakai and Masaka studies sexual behaviour

	Rakai		Masaka		Mwanza	
	M	F	M	F	M	F
Age of debut (y)	17.4	15.8	17.7	16.4	15.0	15.3
Sex partners (%)						
5+ recent	1.4	0.1	2.1	0.0	9.6	1.0
10+ lifetime	34.4	3.1	24.3	3.5	45.2	3.1
Age difference (y)						
Marital (M-F)	5.2	5.0			5.0	8.0
Casual (M-F)	2.5	3.0			5.0	2.0
Condom use (%)						
Always	20.3	5.9			2.1	0.1
Last contact	21.0	11.5	27.7	14.9		

Orroth MoOrD1085

Mwanza, Rakai and Masaka Adjusted STI prevalence

And higher rates of curable STI, as shown in this slide, so that the fraction of HIV transmission that could be attributed to STI in Mwanza was substan-

Slide 12. Mwanza, Rakai and Masaka studies sexual behaviour

	Rakai		Masaka		Mwanza	
	M	F	M	F	M	F
NG (13-39y)*	1.0	1.9	0.9	1.8	2.8	2.3
CT (13-39y)*	2.7	3.2	2.2	1.6	2.3	13.0
TV (15-49y)*		30.8				41.9
High titre syphilis (15-54y)	2.3	1.4	1.2	0.7	5.6	6.3
Serological syphilis (15-54y)	7.7	7.2	4.5	3.9	7.3	8.9
HSV-2 (15-29y)**	21.0	42.8	16.8	44.2	13.3	47.4

*Adjusted for diagnostics
**Rk adjusted for sampling, Mk and Mw for diagnostics
Orroth MoOrD1085

tially higher than in Rakai or Masaka. Thus the take-home message is that STI management is both an important component of primary health care in and of itself and an effective HIV prevention strategy. Its impact will be most prominent in populations with a high incidence of bacterial STIs and a high incidence of HIV.

STIs and HIV

So, if STI treatment is an important part of HIV prevention, what is the best way to deliver it? Three papers examined presumptive treatment for bacterial STIs in female sex workers working in a mining community in South Africa[48] and in urban settings in Kenya[49] and the Philippines[50]. All used 1 gram of azithromycin as the basic treatment, and all showed to various extents that mass treatment could effectively decrease the burden of bacterial STI in these women and presumably their risk of acquiring HIV.

Slide 14. HIV and STI

- Presumptive treatment of bacterial STIs with azithromycin in sex workers
  - South Africa - Steen (TuOrD1150)
  - Kenya - Kimani (TuOrD1151)
  - Philippines - Ramos (TuOrD1152)
- Pharmacists as providers of STI care
  - South Africa - Ward (TuOrD1155)

A study in the Western Cape of South Africa examined pharmacists as potential providers of STI services[51]. Ward and colleagues found that while pharmacists had limited knowledge of correct STI syndromic management, over 97% were willing to provide syndromic STI treatment. This is an untapped resource that may offer a relatively inexpensive method of extending STI treatment services.

Vaginal microbicides

With the demise of nonoxynol-9 several new vaginal microbicides are nearing Phase III trials[53,54]. Three double-blind placebo-controlled trials examined new microbicidal agents in expanded Phase II safety trials. In the first 4% dextrin sulphate gel was not associated with genital epithelial disruption, inflammation or systemic toxicity[55].

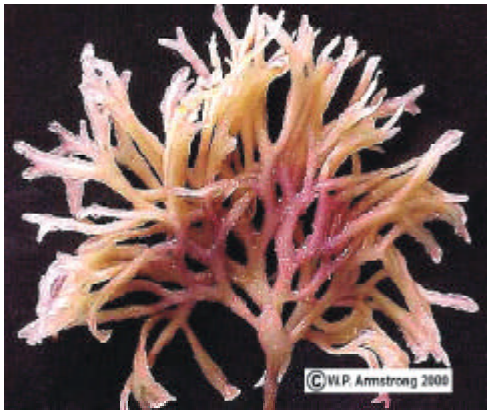
Slide 15. Vaginal microbicides

- In vivo animal data shows suppression of HIV transmission
  - SAMMA - Herold (WeOrD1314)
  - Dapivirine - DiFabio (WeOrD1315)
- Phase II safety trial of 4% dextrose sulfate gel showed no epithelial disruption
  - Low-Beer (WeOrD1318)
- Carraguard safe and acceptable in Phase II trials in South Africa (WeOrD1316) and Thailand (WeOrD1318)

Carraguard®

The other two trials involved the new carrageenan gel, Carraguard®, which was evaluated in South Africa[56] and Thailand[57]. Women were asked to insert the gel three times per week and before each act of intercourse for up to 12 months. At follow up women in the intervention arm were no more likely than women in the placebo gel arm to have visible genital tract abnormalities, in marked distinction to nonoxynol-9. Acceptability is high, and this product is moving on to Phase III trials.

Slide 16. What is Carraguard™?



- Population Council's lead candidate microbicide
- Derived from seaweed (carrageenan)
- Packaged in single-dose Micralax^{R} applicators

Antiretrovirals and HIV transmission

One of the most interesting technological issues in the prevention of HIV transmission-do antiretrovirals decrease the infectiousness of HIV-infected persons -was not examined by a single study in Track D aside from studies of mother-to-child transmission. The lack of research in this area is quite troubling. Clearly opportunities exist for observational studies in countries like Brazil where antiretrovirals are in widespread use and HIV incidence is moderately high, and these should be pursued vigorously.

Slide 17. Role of antiretroviral drugs in preventing HIV transmission

- Track D presentations focused on:
  - Prevention of MTCT
  - Pre-and post-exposure prophylaxis
    - Occupational
    - Non-occupational
  - Treatment optimism (or lack thereof)
- No observational or experimental studies presented on whether antiretroviral therapy decreases sexual infectiousness

Nevirapine plus zidovudine trials

The route of transmission for which antiretroviral therapy has been used most effectively to prevent infection has been from mother to child, and successful regimens continue to be refined.

Taha and colleagues reported on a trial in progress in Malawi of adding zidovudine to the basic nevirapine regimen for newborns[64,65]. They examined the situation in which an HIV-infected mother presents just prior to delivery and cannot receive nevirapine. Babies of these mothers were randomized to get either a single dose of nevirapine or nevirapine plus one week of zidovudine. They found that the addition of zidovudine to the newborn's nevirapine regimen -as shown in this slide- conferred a significant advantage, reducing overall transmission at 6 weeks of follow up from 22% to 14% and among babies who were uninfected at birth from 13% to 7%.

Slide 18. Antiretrovirals for prevention of MTCT Nevirapine plus zidovudine, Malawi. Unadjusted % HIV infected by randomization status

Outcome	NVP plus ZDV	NVP Only	P-Value
HIV+at Birth	8.3% (44/528)	10.5% (55/525)	0.25
HIV+at 6 wks	14.4% (66/459)	21.9% (98/448)	0.004
HIV+at 6 wks among HIV-at birth	6.9% (29/422)	13.3% (49/399)	0.009

Taha (ThOrD2146)

Ditrame Plus

A similar zidovudine plus nevirapine regimen was evaluated in Côte d'Ivoire in the Ditrame Plus study[66]. This is a non-randomized therapeutic cohort study in which both mothers and babies receive zidovudine plus nevirapine. Of 141 children who have been followed through six weeks, the HIV transmission rate is 7.1%.

Slide 19. Peripartum transmission and short term (6 weeks) efficacy of AZT + NVP vs AZT, ANRS 1201, Côte d'Ivoire

	AZT + NVP (Ditrame Plus)	AZT (Ditrame)
Children analysed	240	331
Children infected	16	41
Rate of transmission (%)	7.1	12.8
AZT + NVP crude relative efficacy (%) 44.5%, p = 0.032		

Dabis (ThOrD1428)

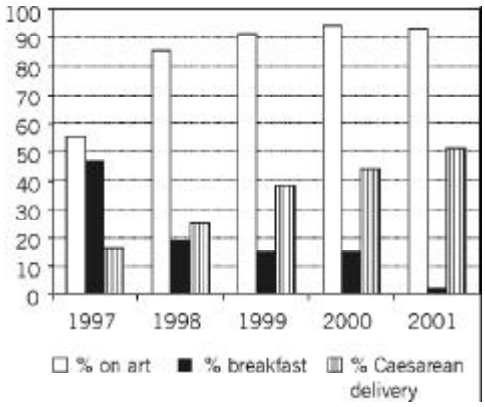
Scaling up for MTCT prevention, Santos, Brazil

Several presentations dealt with how to scale up programs to prevent mother-to-child transmission. I wanted to highlight one real-life example in Brazil[71]. In Santos a zidovudine monotherapy regimen based on ACTG 076 has been used in combination with Caesarean section. From 1997 to 2001 the number of infected babies fell from 12 to 1 coincident with increases in the proportions of women and babies receiving zidovudine and the proportion of women delivered by Caesarean section.

Pre and post-exposure prophylaxis: non-occupational exposure

Turning to post-exposure prophylaxis, a new indication is emerging for non-occupational, predominantly

Slide 20. Scaling up for MTCT prevention, Santos, Brazil



HIV + babies fell from 12 in 1997 to 1 in 2000

Lacerda (ThPpD2148)

sexual exposures, which was highlighted in several presentations.

Two large registries from Europe and the United States followed 700 individuals receiving post-exposure prophylaxis for non-occupational exposures[78,79]. Nine to 13 percent of patients stopped therapy because of adverse effects. Additionally two of these 700 patients seroconverted despite therapy. However, a welcome report from the Congo reported that among 111 women and girls who had received antiretroviral therapy following rape, none developed HIV infection and only three experienced clinical side effects[80].

HIV vaccine trials

And finally vaccines. The first Phase III HIV vaccine trials, using bivalent recombinant gp120 HIV-1 proteins are currently underway in the North America and Europe[90] and in Thailand[91]. Interim reports from these trials noted no serious adverse events, and there have been no modifications requested by data monitoring and safety boards. The two trials are scheduled to end in late 2002 and late 2003 respectively.

Slide 21. Pre- and post-exposure prophylaxis Non-occupational exposures

- 9-13% of patients receiving non-occupational PEP discontinue because of side effects, 2/700 seroconverted - Grohskupf (MoOrD1107), Simon (MoOrD1108)
- No HIV and no severe side effects when ART used post rape in Congo - Belanger (MoOrD1109)
- Phase I/II trial of pre-exposure NVP x12 wks showed no adverse effects, no seroconversions and $[NVP]_{trough} > ID_{50}$ - Jackson (MoOrD1115)

Slide 22. HIV vaccine trials

- First Phase III trial underway of AIDSVAX® B/B rgp120 vaccine in MSM, high-risk heterosexual women in North America and Europe and of B/E in IDU in Thailand
  - No severe adverse effects
  - DMSB (q 6mo) has not stopped trial
  - Ending late 2002 and late 2003
  - Harro (WeOrD1299), Choopanya (WeOrD1302)

Summary

Track D rapporteur team and HIVInsite web site

In sum Track D provided a wealth of new data. Challenges certainly remain, and I would urge you to continue designing and carefully evaluating both behavioral and biomedical interventions.

Finally let me thank the members of the Track D rapporteur team who did such an outstanding job this week capturing the new science that was presented here.

This presentation is available on the HIVInSite web site.

Slide 23. Track D rapporteur team

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For report and references please visit http//:hivinsite.ucsf.edu

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