

# MICROBICIDES

12-15 May 2002

Antwerp, Belgium



Conference Programme



## Welcome from the Conference Chair

At this very moment, when "Microbicides 2002" starts, over 40 million people worldwide are living with HIV and every day an estimated 15.000 new infections occur.

While it is urgent that the already available knowledge in Prevention and Care is implemented on a much larger scale, the need for additional "biomedical" tools to reduce the number of new infections and to minimise the impact of the disease is obvious.

The need for Female Controlled Methods to reduce the sexual transmission of HIV is now widely recognized. Any microbicide, which can prevent or reduce transmission, may ultimately have a dramatic effect on the course of the epidemic.

Despite the many unknowns in this field, today we are hopeful. There is increased public and private interest, with increased levels of funding available. Several promising candidate products are in the pipeline, and currently under evaluation in clinical trials.

The understanding of the scientific, cultural, ethical and economic barriers to the development of such products has improved. And the commitment by individuals and communities to win this battle has never been as strong as it is today.

"Microbicides 2002" in Antwerp, a follow-up of "Microbicides 2000" in Washington, should provide the opportunity for fruitful collaboration and exchange of knowledge among the different disciplines and countries. And hopefully, will push the field ahead, and bring us closer to a new tool to widen our prevention options.

Enjoy the conference and Welcome to the city of Antwerp!

Marie Laga  
Conference chair



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## This meeting is organised in collaboration with

Alliance for Microbicide Development  
 American Foundation for AIDS Research (amfAR)  
 Center for Health and Gender Equity  
 Centers for Disease Control and Prevention (CDC)  
 European Commission  
 Contraceptive Research and Development Program (CONRAD)  
 Family Health International (FHI)  
 Harvard AIDS Institute (HAI)  
 International AIDS Society (IAS)  
 Joint United Nations Programme on HIV/AIDS (UNAIDS)  
 National Institutes of Health (NIH)  
 Population Council  
 United States Agency for International Development (USAID)

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Centers for Disease Control and Prevention	CONRAD	DANIDA
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International AIDS Society	Janssen Research Foundation	
Office of AIDS Research	Pannoc Chemie	Personal Products Company
Population Council	SAREC	The Rockefeller Foundation
The Wellcome Trust	Tibotec NV	UNAIDS
United States Agency for International Development	World AIDS Foundation	World Health Organization



## Organising Committee Members

### Advisory Board Members

**Conference Chair:** Marie Laga, Institute of Tropical Medicine, Belgium

**Co-Chair:** Mark A. Wainberg, McGill AIDS Centre, Jewish General Hospital, Canada

**Scientific Coordinator:** Lut Van Damme, CONRAD, USA

### Organising Committee Members:

Deborah Anderson, Brigham and Women's Hospital, USA  
Jan Balzarini, Rega Institute, Belgium  
Roberta Black, National Institute of Allergy and Infectious Diseases, NIH, USA  
Nicol Coetzee, University of Cape Town, South Africa  
Robert W. Coombs, University of Washington, USA  
Henry L. Gabelnick, CONRAD, USA  
Polly F. Harrison, Alliance for Microbicide Development, USA  
Isabelle Heard, Hôpital Européen Georges Pompidou, France  
Peter Kilmarx, CDC, Thailand  
Charles Lacey, Imperial College School of Medicine, UK  
Preston Marx, Aaron Diamond Research Center and Tulane University of Public Health, USA  
Christine Mauck, CONRAD, USA  
Kenneth H. Mayer, The Miriam Hospital, USA  
Elizabeth McGrory, Population Council, USA  
Susan Newcomer, Demographic and Behavioral Sciences Branch (NICHD), NIH, USA  
Andrew Nunn, Medical Research Council, UK  
Nancy S. Padian, University of California, USA  
Lynn A. Paxton, Centers for Disease Control and Prevention, USA  
David M. Phillips, Population Council, USA  
Gita Ramjee, Medical Research Council, South Africa  
Patricia S. Reichelderfer, National Institute of Child Health and Human Development, NIH, USA  
Zeda F. Rosenberg, Family Health International, USA  
Christine Rouzioux, Hôpital Necker – Enfants Malades, France  
Robin Shattock, St. George's Hospital Medical School, UK  
Jeff Spieler, Office of Population, USAID, USA  
Guido Vanham, Institute of Tropical Medicine, Belgium  
Fulvia Veronese, NIH Office of AIDS Research, USA

### Advisory Board Members

Arthur J. Ammann, Global Strategies for HIV Prevention, USA  
Jennifer Attonito, American Foundation for AIDS Research, USA  
Samuel H. Avrett, AIDS Vaccine Advocacy Coalition, USA  
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Victoria Cargill, NIH, USA  
Ward Cates Jr., Family Health International, USA  
Verapol Chandeying, Prince of Songkla University, Thailand  
Susan F. Crane, International Family Health, UK  
Lieve Franssen, European Commission, Belgium  
Lori Heise, PATH, USA  
Sharon L. Hillier, University of Pittsburgh, Magee Women's Hospital, USA  
John Moore, Cornell University, USA  
Michael A. Parniak, Lady Davis Institute for Medical Research, Canada  
Joseph Perriens, Joint United Nations Programme on AIDS, Switzerland  
Michel Pletschette, European Commission, Belgium  
Helen Rees, University of the Witwatersrand, South Africa  
Jane Silver, American Foundation for AIDS Research, USA  
William Snow, AIDS Vaccine Advocacy Coalition, USA  
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Jonathan Weber, Imperial College School of Medicine at St. Mary's Hospital, UK  
Julie Welch, Family Health International, USA  
Leopold Zekeng, National AIDS Committee and National Research Programme on AIDS, Cameroon

## General Information

- ✓ All participants who made their own travel reservations are requested to confirm their return flights upon arrival at the hotel. Tickets provided by the Conference organisation will be confirmed by the organisers.
- ✓ Lunch is not foreseen in the conference programme. Many snackbars and restaurants are located in the immediate vicinity of the conference venue, some even in the zoo garden itself.
- ✓ During the conference, all registered participants will have free access to the zoo.
- ✓ The conference organisers are not responsible for any accidents, loss or medical emergency during the conference. All participants have been requested to take out their personal insurance to that effect.
- ✓ On the day of departure, Brussels International Airport Zaventem can be reached by Sabena bus (departure near Central Station, bus stop "Keizerlei" every hour on the hour), the trip takes approximately one hour, or by train from Central Station to Brussels National Airport: there is a train every 15 minutes, with a stopover at "Brussel Noord". Antwerp Airport Deurne can be reached by taxi (approx 12 Euro).
- ✓ Poster sessions will be held in the Loos hall from Monday till Wednesday during coffee and lunch breaks, and also on Monday evening from 17:30 hrs. onwards.

The African wall hangings which decorate the conference halls are original works by Mrs Amina Grell from Cameroon. Mrs Grell lives in France in a little village south of Poitiers in the Vienne region, where she has set up an African Textile Art workshop.



**Amina GRELL** – Artisan d'Art Textile  
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## Tracks

### Track A – Basic Science:

- ✓ New agents and formulations
- ✓ Rectal Microbicides and additional selected abstracts
- ✓ Models for Microbicide development: *ex vivo* and animal
- ✓ Mucosal immunology / Pharmacology
- ✓ HIV entry and entry inhibitors

### Track B – Clinical Science:

- ✓ Update & Issues in Microbicide development
  - Spread assessment techniques
- ✓ Phase I and Phase II safety trials
- ✓ Rectal studies and cervical barrier methods
- ✓ Phase III trial design and implementation
  - Operational issues

### Track C – Behavioural Sciences, Public Health & the Microbicide Marketplace:

- ✓ Update & Issues in Microbicide development
- ✓ Acceptability
- ✓ Pharmaco-economics
- ✓ Ethical aspects and advocacy

## Agenda At-a-Glance

### Sunday, May 12

13:00	Registration	Verlat hall
16:30	Opening ceremony	Marble hall
17:30	Tribute to Zena Stein	Marble hall
17:45	Reception	

### Monday, May 13

09:00	Plenary Session	Marble hall
10:30	Break	
10:45	Concurrent Sessions	
	Track A: New agents and formulations	Foyer
	Track B/C: Update & issues in Microbicide development	Marble hall
13:00	Lunch	
14:00	Concurrent Sessions	
	Track A: Rectal Microbicides and additional selected abstracts	Foyer
	Track B: Phase I and Phase II studies	Darwin hall
	Track C: Acceptability	Marble hall
17:30	Poster Session	Loos hall
	NIH Symposium	Marble hall

### Tuesday, May 14

09:00	Plenary Session	Marble hall
10:30	Break	
10:45	Concurrent Sessions	
	Track A: Models for Microbicide development: <i>ex vivo</i> and animal	Foyer
	Track B: Rectal studies and cervical barrier methods	Darwin hall
	Track C: Pharmaco-economics	Marble hall
13:00	Lunch	
14:00	Concurrent Sessions	
	Track A: - Mucosal immunology / Pharmacology	Foyer
	- HIV entry and entry inhibitors	Foyer
	Track B: Phase III trial design and implementation	Darwin hall
	Track C: Ethical aspects and advocacy	Marble hall
17:30	FHI and Rockefeller Foundation Symposium	Darwin hall

### Wednesday, 15 May

09:00	Summary of all tracks	Marble hall
11:00	Conclusions and closing remarks	Marble hall



# Full Conference Agenda

## Sunday 12 May 2002

13:00	<b>Registration</b>	Verlat hall
16:30	<b>Opening ceremony</b> chairs: Marie Laga ( <i>Institute of Tropical Medicine, Belgium</i> ) Mark Wainberg ( <i>McGill University AIDS Centre, Canada</i> )  Arnd Hoeveler ( <i>EC representative</i> )  Peter Piot ( <i>Executive Director UNAIDS, Switzerland</i> )  Kim Dickson-Tetteh ( <i>Chris Hani Baragwanath Hospital, South Africa</i> )  Charlotte Watts ( <i>London School of Hygiene and Tropical Medicine, U.K.</i> )	Marble hall
17:30	<b>Tribute to Zena Stein</b>	
17:45	<b>Reception</b>	

**Monday 13 May 2002**

- 09:00 **Plenary session** **Marble hall**  
 chair: Henry Gabelnick (*CONRAD, USA*)
- Peggy Johnston** (*NIH, USA*)  
 Analogies between vaccine and microbicide research
- David Wilkinson** (*Medical School Adelaide University, Australia*)  
 Nonoxynol-9 spermicide for prevention of HIV and other sexually transmitted infections: systematic review and meta-analysis of randomised controlled trials (P-285)
- Guy Van den Mooter** (*K.U. Leuven, Belgium*)  
 The formulation of vaginal microbicides (P-294)
- 10:30 **Coffee break** **Loos hall**
- 10:45 **Concurrent sessions**

**Track A – Basic Science****Foyer****NEW AGENTS AND FORMULATIONS**

- chairs: Mark Wainberg (*McGill University AIDS Centre, Jewish General Hospital, Canada*)  
 Sanjay Garg (*National Institute of Pharmaceutical Education and Research, India*)
- 10:45 Erik De Clercq (*Rega Institute, Belgium*)  
 Potential candidate anti-HIV microbicides (A-287)
- 11:15 Robin Maguire (*The Population Council, USA*)  
 Lessons from Carraguard™ (A-335)
- 11:45 Katrien Princen (*Rega Institute, Belgium*)  
 Chemokine receptor antagonists as HIV entry inhibitors (A-220)
- 11:55 Joseph Romano (*Biosyn Inc., USA*)  
 UC-781 activity against nonclade B isolates of HIV-1: implications for microbicide development (A-254)
- 12:05 Yven Van Herrewege (*Institute of Tropical Medicine, Belgium*)  
 Microbicidal activity of Dapivirine (TMC-120) and UC-781 in an *in vitro* model for prevention of sexual HIV transmission (A-274)
- 12:15 Alexander Cole (*UCLA School of Medicine, USA*)  
 Retrocyclins: circular minidefensins with potent activity against HIV-1 (A-048)
- 12:25 Kaustubh Tambwekar (*National Institute of Pharmaceutical Education and Research, India*)  
 Effect of different bioadhesive polymers on performance characteristics of vaginal tablets (A-145)
- 12:35 Sarah Kieweg (*Duke University, USA*)  
 Rheological properties of microbicidal formulations governing spreading and retention in the vagina and rectum (A-244)
- 12:45 Discussion



## Joint Session Track B & C

Marble hall

### UPDATE & ISSUES IN MICROBICIDE DEVELOPMENT

chairs: Salim Abdool S. Karim (*University of Natal, South Africa*)  
Alan Stone (*Medical Research Council, U.K.*)

- 10:45 Polly Harrison (*Alliance for Microbicide Development, USA*)  
Products in the pipeline: overview, change, lessons and implications (B/C-326)
- 11:05 Elizabeth Bukusi (*University of Nairobi, Kenya*)  
Regulatory issues in microbicide development – pre clinical requirements (B/C-305)
- 11:20 Sheena McCormack (*Medical Research Council, U.K.*)  
Regulatory issues in clinical safety studies (B/C-325)
- 11:35 Janneke van de Wijgert (*The Population Council, USA*)  
Regulatory issues in clinical effectiveness trials (B/C-301)
- 11:50 Christine Mauck (*CONRAD, USA*)  
Colposcopy (B/C-308)

### Spread Assessment Techniques

- 12:05 Kurt Barnhart (*University of Pennsylvania Medical Center, USA*)  
Non-invasive imaging of the spread of microbicides with magnetic resonance imaging (B/C-283)
- 12:15 David Katz (*Duke University, USA*)  
Measurement, analysis and interpretation of vaginal gel coating distributions in women (B/C-299)
- 12:25 Discussion
- 13:00 **Lunch** (on your own)
- 14:00 **Concurrent sessions**

## Track A – Basic Science

Foyer

### RECTAL MICROBICIDES AND ADDITIONAL SELECTED ABSTRACTS

chairs: Robert Coombs (*University of Washington, USA*)  
Mike Youle (*Royal Free Centre for HIV Medicine, UK*)

- 14:00 Peter Anton (*UCLA AIDS Institute, USA*)  
Biology of the Rectum
- 14:20 Robert Coombs (*University of Washington, USA*)  
Short-term variation and correlates of rectal HIV-1 shedding (A-323)
- 14:40 Scott Brodie (*University of Washington Medical Center, USA*)  
Persistent HIV replication in rectal mucosa, T cells and macrophages during potent antiretroviral therapy (A-291)
- 15:00 Dorothy Patton (*University of Washington, USA*)  
The pig-tailed macaque rectum model (A-286)

- 15:20 Joel Palefsky (*University of California San Francisco, USA*)  
Anal colposcopy (A-304)
- 15:40 **Coffee break** Loos hall
- 16:00 David Phillips (*The Population Council, USA*)  
Effect of N9 on the human rectal mucosa (A-066)
- 16:10 Sarah Kieweg (*Duke University, USA*)  
Mechanisms of vaginal/rectal coating by microbicial formulations: macro-scale processes (A-261)
- 16:20 Brid Burruano (*Biosyn Inc., USA*)  
Physical characterization of an artificial cervical mucus (A-252)
- 16:30 Bradley Catalone (*Penn State College of Medicine, USA*)  
Impact of microbicides on the function of cells derived from the genital tract (A-194)
- 16:40 Frank Piatak (*The Population Council, USA*)  
Modeling dendritic cells-immunodeficiency virus interactions using chemically inactivated virus (A-024)
- 16:50 Charlene Dezzutti (*Centers for Disease Control and Prevention, USA*)  
An *in vitro* algorithm to compare toxicity and anti-viral activity of candidate microbicides for prevention of vaginal and rectal HIV-1 transmission (A-102)
- 17:00 Frédéric Baribaud (*University of Pennsylvania, USA*)  
Modifications in the cytoplasmic domain of HIV-1 env allow exposure of the conserved coreceptor-binding site and enhance neutralization sensitivity (A-029)
- 17:10 Charles Isaacs (*NYS Institute for Basic Research in Development Disabilities, USA*)  
Combination microbicial mixtures inactivate Herpes Simplex Virus (HSV) (A-058)
- 17:20 Discussion

## Track B – Clinical Science

Darwin hall

### PHASE I AND PHASE II STUDIES

- chairs: Suniti Solomon (*YRG Care, India*)  
Kenneth Mayer (*The Miriam Hospital, USA*)
- 14:00 Christine Mauck (*CONRAD, USA*)  
Single and multiple exposure tolerance study of three concentrations of C31G: once- and twice- daily exposure (B-096)
- 14:15 Michel Bergeron (*Laval University, Canada*)  
Phase I clinical trial to evaluate the safety and acceptability of the invisible condom™ when applied intravaginally to healthy female subjects (B-151)
- 14:30 Kamal Hazari (*Institute of Research in Reproduction, India*)  
Phase I safety study with pranem polyherbal vaginal tablet (B-278)
- 14:45 Charles Lacey (*Imperial College of Science, Technology and Medicine, U.K.*)  
Pro 2000 achieves potentially protective levels against HIV in cervico-vaginal lavage in a vaginal microbicide safety study (B-059)



- 15:00 Michael Bukenya (*Medical Research Council, Uganda*)  
A phase II study of the safety of Dextrin sulphate gel in sexually active females in Kampala (B-025)
- 15:15 Discussion
- 15:30 **Coffee break** **Loos hall**
- 15:45 Nicol Coetzee (*University of Cape Town, South Africa*)  
A randomized, placebo-controlled double-blind safety trial of Carraguard™ microbicide gel in South Africa: signs and symptoms of genital irritation (B-069)
- 16:00 Peter Kilmarx (*CDC, Thailand*)  
Incidence of irritation and genital lesions in a year-long, randomized, controlled clinical trial of a carrageenan gel as a vaginal microbicide (B-227)
- 16:15 Sharon Hillier (*University of Pittsburg, Magee Women's Hospital, USA*)  
Sexual behaviors of women enrolled in a microbicide trial of *Lactobacillus Crispatus* CTV 05 in the United States (B-249)
- 16:30 Marianne Callahan (*CONRAD, USA*)  
Safety and tolerance studies of potential microbicides following multiple penile applications (B-303)
- 16:45 Connie Celum (*University of Washington Harborview Medical Center, USA*)  
Safety and acceptability of Buffergel® and Pro 2000/5 gel in HIV+ men (B-149)
- 17:00 Vicky Jaspers (*Institute of Tropical Medicine, Belgium*)  
Penile application of dextrin sulphate gel (Emmelle®) to HIV+ and HIV- men (B-235)
- 17:20 Discussion

**Track C – Behavioural Science, Public Health and the Microbicide Marketplace** **Marble hall**

**ACCEPTABILITY**

chairs: Susan Newcomer (*Demographic and Behavioral Science Branch, NICHD, USA*)  
Discussant: Alain Giami (*Inserm U 292, France*)

- 14:00 **Theories Panel:**
- Isabel Fernandez (*University of Miami School of Medicine, USA*)  
That was then, this is now: how acceptability changes over time
  - S. Marie Harvey (*Center for the Study of Women in Society, USA*)  
Acceptability of the vaginal diaphragm among a sample of women in the US: comparing current and former diaphragm users (C-297)
  - Gita Ramjee (*Medical Research Council, South Africa*)  
Acceptability studies in South Africa: past, present and future (C-306)
  - Susan Rosenthal (*UTMB Children's Hospital, USA*)  
Adolescent girls and topical microbicides: attitudes of health care providers (C-298)
  - Cynthia Woodsong and Hellen Koo (*FHI and RTI, USA*)  
Holistic view of acceptability among a multi-ethnic population of adult and teen women and men (C-293)
  - Stephen Weiss (*University of Miami School of Medicine, USA*)  
Influencing barrier acceptability and use among women living with HIV: a conceptual framework

15:45 **Coffee break** Loos hall

**In practice**

- 16:00 Susie Hoffman (*New York State Psychiatric Institute and Columbia University, USA*)  
Provider's attitudes about Nonoxynol-9 (N-9): an impediment to promoting microbicides? (C-137)
- 16:10 Abigail Norris Turner (*The Population Council, Mexico and South Africa*)  
Telling the truth in microbicide trials: using audio computer-assisted self-interview (ACASI) to assess the accuracy of self-reported behavioral data in a phase II clinical trial (C-242)
- 16:20 Ethel Qwana (*Medical Research Council, South Africa*)  
Sex workers' belief, experiences and perceptions of COL-1492 in Durban, South Africa (C-130)
- 16:30 Lut Van Damme (*CONRAD, USA*)  
Acceptability of vaginal, gel COL-1492, as a protective barrier against HIV in African and Asian sex workers (C-233)
- 16:40 Julie Pickering (*Medical Research Council, Uganda*)  
Influences on recruitment to a phase II microbicide trial in urban Uganda: HIV testing and condom use (C-118)
- 16:50 Heidi Jones (*The Population Council, USA and South Africa*)  
Vaginal product use by phase II microbicide trial participants in South Africa (C-126)

17:00 Discussion

17:30 **Poster Session** Loos hall

17:30 **NIH Symposium** Marble hall

***In vitro, in vivo, and in the vagina, the story of N9***

The objective of the symposium will be to critically review the published and unpublished data from preclinical and clinical safety studies that tested N9 and N9-containing microbicides for the purpose of gaining a better understanding of which assays or models may predict safety in order to inform microbicides clinical trials. Issues to be discussed include: dosing, timing, frequency of use, formulations, and relevancy of models.

17:30 Welcome  
Fulvia Veronese (*NIH Office of AIDS Research, USA*)

17:35 Introduction  
Sharon Hillier (*University of Pittsburgh, Magee Women's Hospital, USA*)

17:40 *In vitro* and *ex vivo* models  
Robin Shattock (*St. George's Hospital Medical School, U.K.*)

18:00 Animal models  
Thomas Moench (*Johns Hopkins and ReProtect, USA*)

18:20 Clinical and behavioral studies  
Sharon Hillier (*University of Pittsburgh, Magee Women's Hospital, USA*)

**Round table discussion**

Moderator: Fulvia Veronese (*NIH Office of AIDS Research, USA*)



## Tuesday 14 May 2002

- 09:00 **Plenary session** **Marble hall**  
chair: Deborah Anderson (*Brigham and Women's Hospital, USA*)
- Rupert Kaul** (*University of Toronto, Canada*)  
The role of mucosal immunity in HIV-1 susceptibility and transmission (P-300)
- Roberta Black** (*NIAID, USA*)  
Preclinical and clinical safety - a critical review (P-324)
- Elizabeth McGrory** (*The Population Council, USA*)  
Preparing for microbicide access and use: policy priorities (P-317)
- 10:30 **Coffee break** **Loos hall**
- 10:45 **Concurrent sessions**

### Track A – Basic Science

Foyer

#### MODELS FOR MICROBICIDE DEVELOPMENT: *EX VIVO* AND ANIMAL

- chairs: David Phillips (*The Population Council, USA*)  
Martin Cranage (*CAMAR, U.K.*)
- 10:45 Ronald Veazey (*Tulane Regional Primate Research Center, USA*)  
SIV in the anorectal system (A-327)
- 11:05 Chris Miller (*University of California at Davis, USA*)  
Insights from the biology of vaginal SIV transmission that impact microbicide development (A-330)
- 11:25 Roger Le Grand (*DSV/DRM, France*)  
Primate models of AIDS for testing preventive methods of HIV transmission (A-312)
- 11:45 Mary Jo Burkhard (*North Carolina State University, USA*)  
The feline (FIV) model: relevance for assessing microbicides (A-289)
- 12:05 Robin Shattock (*St. George's Hospital Medical School, U.K.*)  
*Ex vivo* human cultures for assessing microbicides (A-314)
- 12:25 James Cummins (*Centers for Disease Control and Prevention, USA*)  
A cervical explant model for safety and efficacy testing of topical microbicides for the prevention of sexual HIV transmission (A-101)
- 12:35 Tina Kish (*Penn State College of Medicine, USA*)  
A small animal model for the study of Human Immunodeficiency Virus –1 infection in human vaginal xenografts (A-162)
- 12:45 Alisen Petersen (*University of Washington, USA*)  
Topical microbicide safety studies conducted in the *Macaca nemestrina* model (A-184)

**Track B – Clinical Science**

Darwin hall

**RECTAL STUDIES AND CERVICAL BARRIER METHODS**

chairs: Nancy Padian (*University of California, USA*)  
Gita Ramjee (*Medical Research Council, South Africa*)

**Rectal Microbicide use**

- 10:45 Kenneth Mayer (*The Miriam Hospital, USA*)  
Methodological challenges in the evaluation of rectal microbicides (B-321)
- 11:00 Connie Celum (*University of Washington Harborview Medical Center, USA*)  
Clinical experience with Nonoxynol-9 (B-311)
- 11:15 Galen Cortina (*UCLA School of Medicine, USA*)  
Safety issues
- 11:30 Discussion

**Cervical barrier methods**

- 11:45 Thomas Moench (*ReProtect, LLC, USA*)  
The cervix and new barriers (B-316)
- 12:00 Craig Cohen (*University of Washington, USA*)  
The diaphragm: a female controlled method to prevent HIV and other sexually transmitted infections? (B-288)
- 12:15 Mitchell Warren (*The Female Health Company, USA*)  
Introducing new female-initiated methods: what we've learned from history and what it means for microbicides (B-307)
- 12:30 Anna Parsons (*University of South Florida, USA*)  
Uterine uptake of vaginal fluids: implications for microbicides (B-175)
- 12:45 Discussion

**Track C – Behavioural Science, Public Health and the Microbicide Marketplace** Marble Room**PHARMACO-ECONOMICS**

chairs: Andrew Nunn (*Medical Research Council, U.K.*)  
Helen Rees (*University of the Witwatersrand, South Africa*)

- 10:45 Arnon Mishkin (*Boston Consulting Group, USA*)  
Potential market for microbicides (C-331)
- 11:15 Bethany Holt (*UCBerkeley School of Public Health, USA*)  
The market potential for Microbicides: young US women (C-284)
- 11:30 Sanjay Garg (*National Institute of Pharmaceutical Education and Research, India*)  
Survey of marketed vaginal formulations in India (C-076)
- 11:45 Discussion



- 12:00 **Panel**
- Charlotte Watts (*London School of Hygiene and Tropical Medicine, U.K.*)  
New hope for HIV prevention: projections of the impact of microbicides (C-319)
  - Peter Vickerman (*London School of Hygiene and Tropical Medicine, U.K.*)  
Determinants of microbicide impact: model predictions from two African settings (C-318)
  - Anna Foss (*London School of Hygiene and Tropical Medicine, U.K.*)  
Migration from the condom: should we be concerned? (C-315)
  - Lilani Kumaranayake (*London School of Hygiene and Tropical Medicine, U.K.*)  
Ensuring microbicide access: public/private roles in low and middle income countries

13:00 **Lunch** (on your own)

14:00 **Concurrent sessions**

## Track A – Basic Science

Foyer

### 1) MUCOSAL IMMUNOLOGY/ PHARMACOLOGY

chairs: Christine Rouzioux (*Hôpital Necker, France*)  
Liliana Peralta (*National Reference Centre for AIDS, Argentina*)

- 14:00 Charles Wira (*Dartmouth Medical School, USA*)  
Mucosal immunity in the female reproductive tract (A-269)
- 14:20 Florian Hladik (*Fred Hutchinson Cancer Research Center, USA*)  
Immunity in the female genital tract (A-328)
- 14:40 Stephen Taylor (*University of Birmingham Edgbaston, U.K.*)  
HIV-1 drug penetration into the male genital tract: implications for sexual transmission (A-302)

15:00 **Coffee break**

Loos hall

### 2) HIV ENTRY AND ENTRY INHIBITORS

chairs: Paolo Lusso (*DIBIT - San Raffaele Scientific Institute, Italy*)  
Quentin Sattentau (*Imperial College of Science, Technology and Medicine, U.K.*)

- 15:20 Quentin Sattentau (*Imperial College of Science, Technology and Medicine, U.K.*)  
Mechanisms of inhibition of HIV-1 attachment and entry (A-310)
- 15:40 Edward Berger (*NIAID, USA*)  
A novel HIV-1 neutralizing protein based on sequential receptor interactions: potential use as a topical microbicide against sexual transmission (A-275)
- 16:00 Leonid Margolis (*NICHD, NIH, USA*)  
Co-receptor use *ex vivo* (A-313)
- 16:20 Dominique Schols (*Rega Institute, Belgium*)  
CXCR4 inhibitors with potent anti-HIV activity (A-290)
- 16:40 John Moore (*Cornell University, USA*)  
Novel entry inhibitors (A-292)

- 17:00 Paolo Lusso (*DIBIT - San Raffaele Scientific Institute, Italy*)  
Mapping of HIV-inhibitory determinants of chemokines as a strategy for the rational design of novel antiviral molecules (A-117)
- 17:15 Discussion

## Track B – Clinical Science

Darwin hall

### PHASE III TRIAL DESIGN AND IMPLEMENTATION

chairs: Charles Lacey (*Imperial College of Science, Technology and Medicine, U.K.*)  
Anatoli Kamali (*Medical Research Council, Uganda*)

- 14:00 Richard Hayes (*London School of Hygiene and Tropical Medicine, U.K.*)  
Community trials of vaginal microbicides (B-332)
- 14:20 Anne Buvé (*Institute of Tropical Medicine, Belgium*)  
When RCTs may not be the best design (B-295)
- 14:40 Nancy Padian (*University of California San Francisco, USA*)  
When does null effect mean no effect? (B-329)
- 15:00 Anwar Hoosen (*MEDUNSA, South Africa*)  
Measuring STI outcomes
- 15:20 Discussion
- 15:45 **Coffee break** **Loos hall**
- Operational Issues**
- 16:15 Supaporn Chaikummao (*Thailand MOPH – U.C. CDC Collaboration, Thailand*)  
Preparation for clinical trials of vaginal microbicides in Northern Thailand (B-322)
- 16:30 Nicol Coetzee (*University of Cape Town, South Africa*)  
Implementation issues in conducting high quality microbicide clinical trials in a resource-constrained environment (B-296)
- 16:45 Anne Ngondo (*Positive Widows in Kenya, Kenya*)  
Strategies in maintaining high follow-up rate in vaginal microbicides clinical trial (B-221)
- 16:55 Camille Anoma (*Projet RETRO-CI, Côte d'Ivoire*)  
Limiting loss to follow-up rates during a microbicide trial: experience during the COL-1492 trial in Abidjan, Côte d'Ivoire (B-246)
- 17:05 Leopold Zekeng (*Laboratoire de Santé Hygiène Mobile, Cameroon*)  
Randomized controlled trials on vaginal microbicides in Cameroon – Site introduction and lessons from past experience (B-115)
- 17:15 Discussion



## Track C – Behavioural Science, Public Health and the Microbicide Marketplace **Marble Room**

### ETHICAL ASPECTS AND ADVOCACY

chairs: Jeff Spieler (*Office of Population, USAID, USA*)  
Neetha Morar (*Medical Research Council, South Africa*)

#### Ethics

- 14:00 Anthony Japour (*Abbott Laboratories, USA*)  
Where science meets ethics in AIDS clinical trials
- 14:20 Peter Kilmarx (*Thailand CDC, Thailand*)  
Protection of human subjects' rights in microbicide trials: experience and recommendations (C-309)
- 14:40 Leopold Zekeng (*Laboratoire de Santé Hygiène Mobile, Cameroon*)  
Ethics in randomized controlled trials of microbicides in Cameroon: theoretical and practical issues (C-334)
- 15:00 Barbara Friedland (*The Population Council, USA*)  
Informed consent in an expanded safety trial of Carraguard™: lessons learned (C-212)
- 15:15 Katharine Shapiro (*FHI, HIV Prevention Trials Network, USA*)  
Problem-solving ethical issues: a Standard of Care case study discussion
- 15:30 Interactive discussion: "Implementing ethics"

15:45 **Coffee break**

**Loos hall**

#### Advocacy

- 16:00 Lori Heise (*Global Campaign for Microbicides, USA*)  
Microbicides, HIV vaccines, and treatment access: comparing the advocacy challenges (C-333)
- 16:20 Lilja Jonsdottir (*Canadian AIDS Society, Canada*)  
Microbicide advocacy group network (MAG-Net) (C-057)
- 16:35 Princess Olufemi-Kayode (*Journalists Against AIDS, Nigeria*)  
Mobilising media collaboration to accelerate microbicides awareness and development: the Nigeria experience (C-085)
- 16:50 Bobby Ramakant (*India*)  
Tapping free media potential for microbicide advocacy (A-273)
- 17:05 Henriette Ahrens (*National STD/AIDS Program, Brazil*)  
Microbicide – Updating the Brazilian experience (A-239)
- 17:20 **Discussion and Wrap-up**

17:30 **FHI & Rockefeller Foundation Symposium** Darwin hall

***The International Partnership for Microbicides***

This session will present the key findings of working groups convened by the Rockefeller Foundation to examine issues critical to accelerating microbicide development, testing and use. It will also present the International Partnership for Microbicides, a new international effort designed to increase the efficiency with which a safe and effective microbicide can be made available to individuals at risk of HIV infection in resource-poor settings.

*Sponsored by FHI and The Rockefeller Foundation*

## Wednesday 15 May 2002

09:00 **Summary of all tracks** Marble hall

***Track A – Basic Science***

Pat Reichelderfer (*NICHHD, USA*)

***Track B – Clinical Science***

Zeda Rosenberg (*FHI, USA*)

***Track C – Behavioural Science, Public Health and the Microbicide Marketplace***

- Acceptability: Susan Newcomer (*NIH, USA*)
- Market and public health: Polly Harrison (*Alliance for Microbicide Development, USA*)
- Ethics: Gita Ramjee (*Medical Research Council, South Africa*)

10:30 **Coffee break** Loos hall

11:00 **Conclusions and Closing Remarks** Marble hall

Stefano Vella (*IAS; Istituto Superiore di Sanita, Italy*)

Eddy Boutmans (*Belgian State Secretary for Development Cooperation*)

Beatrice Nabulya (*Positively Women, U.K.*)



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## Contacts for Additional Information

# MICROBICIDES 2002

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