

AIDS-RELATED RESEARCH PROJECTS



THE LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

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This booklet summarises current AIDS-related research being conducted by academic staff of the London School of Hygiene & Tropical Medicine, in collaboration with colleagues in 22 countries in Africa, Asia, South America and Europe.

All three Departments in the School are involved in research on AIDS and related conditions, and the work described covers many disciplines: clinical and laboratory-based research, classical and molecular epidemiology, mathematical modelling, demography, social and behavioural sciences, health economics and policy analysis. The School is particularly well known for intervention trials against HIV/AIDS and other sexually transmitted diseases, having conducted a community-randomised trial in Tanzania which showed that improved STI treatment at the primary health care level could reduce HIV incidence by some 40%. In view of the shockingly high incidence of HIV infection in young people, especially girls, in many developing countries, it is right that much effort is focused on the evaluation of interventions in adolescents. Recently, research conducted at the School has focused on the role of non-classical STIs as cofactors of HIV transmission, and on the implications of the HIV/AIDS epidemic on policy, economics and health systems.

The 87 projects summarised in this booklet are set out according to research area, and the School staff involved in each project are listed. Please do not hesitate to contact one of the named individuals if you would like to know more about a specific project. I hope you find this booklet useful.

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Further information on HIV/AIDS/STI research
at the London School of Hygiene & Tropical Medicine can be found at:
<http://www.lshtm.ac.uk/research/dfid/aids/>

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DFID Knowledge Programmes

Title	DFID KNOWLEDGE PROGRAMME ON HIV/AIDS & SEXUALLY TRANSMITTED INFECTIONS
Country	Global
LSHTM staff	<p><u>CRU</u>: David Mabey, Philippe Mayaud, Sarah Hawkes, Duncan McCormick, Debby Watson-Jones, Onno Dekker;</p> <p><u>IDEU</u>: Richard Hayes, Judith Glynn, Heiner Grosskurth, Linda Morison, Jim Todd, Helen Weiss, Richard White;</p> <p><u>HPU</u>: Lilani Kumaranayake, Louisiana Lush, Fern Terris-Prestholt, Charlotte Watts.</p>
Collaborators and collaborating institutions	<p>Co-PI MRC Social & Public Health Research Unit, University of Glasgow, Glasgow, UK (Graham Hart, Danny Wight, Caroline Allen).</p> <p>Key partners:</p> <ul style="list-style-type: none"> • National Institute for Medical Research (NIMR), Mwanza, Tanzania • African Medical and Research Foundation (AMREF), Mwanza, Tanzania • Department of State for Health (DOSH) and MRC Laboratories, the Gambia • Centre National de Référence des MST et du SIDA, Bangui, Central African Republic • Uganda Virus Research Institute (UVRI) and MRC HIV/AIDS Research Unit, Entebbe, Uganda • University of Zimbabwe, Harare, Zimbabwe • Aurum Research Unit, Welkom, South Africa • Population Council, New Delhi, India • Ministry of Health, Beijing, China. <p>Other collaborating institutions:</p> <ul style="list-style-type: none"> • Central Public Health Laboratory, Colindale, UK • Department of STD, University College London Medical School, London, UK • INSERM U 430 & Hôpital Européen Georges Pompidou, Paris, France • Institut de recherche pour le développement (IRD), University of Montpellier, France • World Health Organization (WHO) and UNAIDS, Switzerland • Institute of Tropical Medicine, Antwerp, Belgium • Department of Molecular Diagnostics, Cambridge, UK • Sherbrooke University, Sherbrooke, Canada • University of Laval, Quebec, Canada • University of Manitoba, Winnipeg, Canada • Karonga Prevention Project, Malawi • Kisumu Research Project CDC/KEMRI, Kenya • Society for Applied Studies, Calcutta, India. • West African Project to Combat AIDS (WAPTCA), Ghana • Reproductive Health Research Unit (RHRU), Johannesburg, South Africa • Centre Muraz, Bobo-Dioulasso, Burkina Faso • Institute of Tropical Medicine, Sao Paulo, Brazil
Funding	Department for International Development (DFID), UK
Dates	2001 – 2006

Summary

The Knowledge Programme (KP) is a five-year research and training programme based at the LSHTM and the MRC Social & Public Health Sciences Unit, Glasgow, with collaborators in Africa and Asia, and funded by the Department for International Development (DFID). The KP is working to find the most (cost) effective interventions in disadvantaged populations for the prevention of HIV/STIs and the care of people with HIV/AIDS and STIs.

Purpose

To influence policy and practice towards (cost) effective interventions in disadvantaged populations for the prevention of HIV/STIs and the provision of optimal care for persons with HIV/AIDS and STIs.

Goal

To reduce the transmission of HIV and STIs, and to improve the health of people infected with HIV and STIs, especially among disadvantaged communities.

Specific objectives

- To reduce the incidence of HIV infection and other STIs;
- To improve the quality of life of HIV-positive people, and to estimate the cost and cost-effectiveness of interventions to this end;
- To ensure that the most appropriate interventions are prioritised and implemented as widely as possible.

Enhancing the capacity of collaborating institutions

The KP is working with collaborating institutions to enhance their capacity in research development and communication of research to policymakers and programme implementers. We are achieving this through means such as workshops to identify research agendas and training needs; in-service training in research methods; formal training; jointly developing research proposals; improving laboratory and computing facilities; promoting communication and exchange.

Publications

The KP has established a website, with updated publications lists, and a database with all projects. See at <http://www.lshtm.ac.uk/research/dfid/aids/>

The KP has a regular Newsletter, available on website and circulated electronically:

- Issue No1., March 2002 – Sexual Violence and HIV/AIDS;
- Issue No2., June 2002 – Antiretroviral Drugs;
- Issue No3., October 2002 – STI prevention and Care;
- Issue No4., April 2003 – High-Risk Populations: sex workers and their clients;
- Issue No5., October 2003 – Young people's sexual health.

Title	DFID TUBERCULOSIS PROGRAMME
Countries	UK, India, Nepal, Pakistan, Zambia
LSHTM staff	Peter Godfrey-Faussett, Ruth McNerney, Alexandra Coldham, John Porter, Judith Glynn, Vincent Tihon, Ginny Bond (ITD), Karina Kielmann (PHP)
Collaborators	<ul style="list-style-type: none">• John Walley, James Newell, Sarah Escott, Kamran Siddiqi (Nuffield Institute for Health, Leeds, UK)• Amir Kahn (Association for Social Development, Pakistan)• Sheela Rangan (Centre for Human Resources, India)• Moses Sinkala, Seraphim Kaminsa (Lusaka Urban Health Management Team, Zambia)
Funding	Department for International Development (DFID), UK
Dates	2001 – 2006

Summary

The Tuberculosis Programme links the London School of Hygiene & Tropical Medicine with the Nuffield Institute for Health, Leeds. It is a multidisciplinary programme covering the next five year period. The objectives are to:

- Facilitate closer collaboration between researchers, policy-makers and implementing agencies in the different countries;
- Better understand the social, economic and cultural influences on access to services for TB and adherence to treatment in Southern and West Africa and the Indian sub-continent;
- Develop and test affordable approaches to improving the speed and accuracy of diagnosis;
- Test new strategies to improve coverage and treatment outcome in TB control programmes in Southern Africa, India, Pakistan and Nepal;
- Evaluate innovative ways to promote synergy between services for TB and HIV in countries most affected by the dual epidemic;
- Explore approaches to reduce the threat of multi-drug resistant TB;
- Understand the impact on disease control programmes, of different approaches to Health Sector Reform between Malawi and Zambia;
- Explore the factors that facilitate and constrain the policy transfer of DOTS from international to national contexts in South Africa and Mozambique;
- Develop effective communication strategies to reach international, national and local health and TB policy makers and practitioners.

Chapter 1. Factors that influence sexual behaviour

1.1 Adolescents

Title	SEXUAL BEHAVIOUR OF ADOLESCENTS IN RURAL TANZANIA AND THE IMPACT OF AN INNOVATIVE SEXUAL HEALTH INTERVENTION: HEALTH & LIFESTYLES RESEARCH (HALIRA) PROGRAMME
Country	Tanzania
LSHTM staff	Alessandra Anemona, Heiner Grosskurth, Richard Hayes, Angela Obasi, Mary Plummer (Co-ordinator), David Ross, James Todd
Collaborators	<ul style="list-style-type: none"> • African Medical and Research Foundation (AMREF), Tanzania • Medical Research Council (MRC) Glasgow, UK • National Institute for Medical Research (NIMR), Tanzania
Funding	<ul style="list-style-type: none"> • Medical Research Council (MRC), UK • Department for International Development (DFID), UK • European Commission • Ireland Aid
Dates	January 1999 – June 2004

Summary

This programme of behavioural and social science research is investigating the sexual behaviour of rural adolescents in Mwanza Region, Tanzania. It is closely linked to the Adolescent Reproductive Health Intervention Trial, Mwanza (MEMA kwa Vijana Project).

The programme is using three main qualitative and two main quantitative methods to investigate the sexual behaviour of rural adolescents:

- Participant observation, where young East African researchers each year spend 7 weeks in each of four selected villages, observing the social life of adolescents, including sexual negotiation, etc.
- In-depth interviews with adolescents who are selected based on their HIV and/or pregnancy status that are ascertained within the evaluation component of the MEMA kwa Vijana trial.
- Focus group discussions with young people, mainly about issues that have been found to be difficult to address in questionnaires, in-depth interviews and participant observation.
- Three rounds of face-to-face interviews to all 10,000 members of the impact evaluation cohort of the MEMA kwa Vijana trial.
- Three rounds of self-completion questionnaire interviews by selected members of the impact evaluation cohort of the MEMA kwa Vijana trial and (in the first two rounds only) their younger peers (approximately 6,000 per round).

The programme started in January 1999 and is funded until June 2004. Data collection ended in September 2002.

Publications for 2003 (for earlier publications, see Annual Reports from 2001 and 2002):

Ross D and Wight D. 2003. The role of randomized controlled trials in assessing sexual health interventions. In *Effective sexual health interventions: Issues in experimental evaluation*. Stephenson J, Imrie J, and Bonell C, eds. Oxford University Press.

Wight D and Obasi A. 2003. Unpacking the 'black box': The importance of process data to explain outcomes. In *Effective sexual health interventions: Issues in experimental evaluation*. Stephenson J, Imrie J, and Bonell C, eds. Oxford University Press.

Cowan FM and Plummer M. 2003. Biological, behavioural and psychological outcome measures. In *Effective sexual health interventions: Issues in experimental evaluation*. Stephenson J, Imrie J, and Bonell C, eds. Oxford University Press.

Todd J, Chagalucha J, Ross DA, Mosha F, Obasi AIN, Plummer M, Balira R, Grosskurth H, Mabey DCW, Hayes R. 2003. The sexual health of pupils in years 4 to 6 of primary schools in rural Tanzania *Sexually Transmitted Infections*, in press.

Plummer M. (Forthcoming). How can we collect true information? Increasing the validity and reliability of young people's reported sexual behaviour in developing countries'. In National AIDS Programmes: A Guide to Monitoring and Evaluation. UNAIDS.

Plummer M, Wight D, Ross D, Balira R, Todd J, Anemona A, Salamba Z, Obasi A, Grosskurth H, Changalucha J, Hayes R. (Forthcoming). Asking semi-literate adolescents about sexual behaviour: I. An assisted self-completion questionnaire (ASCQ) survey in rural Tanzania. Submitted to *Tropical Medicine and International Health*.

Plummer M, Wight D, Ross D, Balira R, Todd J, Anemona A, Salamba Z, Obasi A, Grosskurth H, Changalucha J, Hayes R. (Forthcoming). Asking semi-literate adolescents about sexual behaviour: II. Cross-sectional and longitudinal comparisons to assess ASCQ data validity. Submitted to *Tropical Medicine and International Health*.

Wight D, Plummer M, Mshana G, Wamoyi J, Salamba Z and Ross D. (Forthcoming). Contradictory sexual norms and expectations for young people in rural northern Tanzania. Submitted to *Africa*.

Desmond N, Allen C, Clift S, Plummer M, Bugeke G, Justine B, Watson-Jones D, Changalucha J, Ross D. (Forthcoming). A typology of groups at risk of HIV/AIDS/STI in a mining location in northern Tanzania revealed using qualitative methods. Submitted to *AIDS Care*.

Obasi AI, Cleophas B, Ross DA, Chima KL, Gavyole A, Plummer ML, Makokha M, Grosskurth H, Mabey DC, Hayes RJ. (Forthcoming). Rationale and design of an adolescent reproductive health intervention in Mwanza Region, Tanzania. Submitted to *AIDS*.

Wamoyi J. et al. (Forthcoming). Exchanging sex for gifts or money among young people in rural northern Tanzania. Submitted to *Social Science and Medicine*.

Ross DA, Changalucha J, Gavyole A, Todd J, Obasi AIN, Cleophas-Mazige B, Plummer ML, Mosha F, Wight D, Mabey DC, Grosskurth H, Hayes RJ. (Forthcoming). The *MEMA kwa Vijana Project*: The design of a community-randomised trial of the impact of an innovative adolescent sexual health intervention programme in rural Tanzania.

Title	UNDERSTANDING THE SEXUAL HEALTH RISKS TO ADOLESCENTS AFFECTED BY AIDS IN URBAN ZIMBABWE
Country	Zimbabwe
LSHTM staff	Isolde Birdthistle (RD Student), Judith Glynn, Sian Floyd
Collaborators	<ul style="list-style-type: none"> • Simon Gregson (Imperial College, and the Biomedical Research & Training Institute, Zimbabwe) • Doreen Mukwena (Child Protection Society, Zimbabwe) • Tomaida Banda (Highfield Community Child Care Project)
Funding	UNICEF (partial)
Dates	Present – September 2005

Summary

By the end of this decade, 25 million children are expected to have lost one or both parents to AIDS. It is expected that desperate conditions and the absence of adult protection leave orphaned children vulnerable to abuse and sexual exploitation, thereby increasing their vulnerability to HIV infection and perpetuating a cycle of orphanhood, poverty and risk. However, links between orphanhood and HIV risk in adolescents have not been studied directly. Focusing on the experiences of young women in Highfield, Zimbabwe – an urban area in which high adult mortality from AIDS has created an estimated 8000 orphans – we hope to understand how orphanhood and other effects of AIDS influence the circumstances, behaviours and HIV and STI risk of adolescent girls. We will explore individual, family and community level factors that influence the above relationships, either by enhancing or reducing risk among adolescents affected by AIDS. The study will also assess the nature and reach of existing services for adolescents affected by AIDS and identify immediate and future programming needs.

Publications

Birdthistle I. Understanding the Needs of Orphans and Other Children Affected by HIV and AIDS in Africa: The State of the Science. Paper prepared for U.S. Agency for International Development, November 2003.

1.2 High-risk populations

Title	BEHAVIOURAL, IMMUNOLOGICAL AND VIROLOGIC CORRELATIONS OF HIV-1 INFECTION AND SUPERINFECTION IN RURAL TANZANIA
Country	Tanzania
LSHTM staff	Heiner Grosskurth, Gabriele Riedner, David Mabey, Richard Hayes, Basia Zaba, Brent Wolff
Collaborators	<ul style="list-style-type: none">• Michael Hoelscher, Frank von Sonnenburg, Oliver Hoffmann (University of Munich, Germany)• Eligius Lyamuya, Fred Mhalu (Muhimbili University College of Health Sciences, Dar es Salaam, Tanzania)• Leonard Maboko, Donan Mmbando, Eleuter Samki (Mbeya Region Research Board)• Francine McCutchan (Henry Jackson Foundation)• Carolyn Williamson (University of Cape Town, South Africa)
Funding	European Commission (EC)
Dates	July 2000 – June 2005

Summary

HIV infection may potentially be protective against superinfection by a second HIV strain. Whilst co-infections with different HIV strains have been described, only few data are available on the circumstances of such superinfection. This study investigates the prevalence, incidence, and the virologic, immunological, clinical, and social factors associated with superinfection in a cohort of 600 highly exposed barworkers in a mostly rural region of Tanzania, where 3 HIV-1 subtypes co-circulate (A,C,D). The study will help to determine whether superinfection can occur in the presence of a fully developed immune response, will define its natural history and virologic outcomes, including emergence of recombinants, and will provide a new approach to define correlates of protective immunity for vaccine development. Within the collaborative arrangement, LSHTM contributes to the overall implementation of the study, and addresses behavioural and STD related research questions in particular.

Title	THE EPIDEMIOLOGY AND CONTROL OF ULCERATIVE STIS AMONG SEX WORKERS IN MBEYA, TANZANIA AND THEIR INTERACTION WITH HIV INFECTION
Country	Tanzania
LSHTM staff	Gabriele Riedner, Heiner Grosskurth, David Mabey, Richard Hayes, Jim Todd.
Collaborators	<ul style="list-style-type: none">• Eligius Lyamuya, Fred Mhalu (Muhimbili University College of Health Sciences, Dar es Salaam, Tanzania)• Leonard Maboko, Donan Mmbando, Eleuter Samki (MoH Tanzania, Mbeya Region); Phillip Hay (St. George's Hospital, London, UK)• Anne Buvé, Eddy Van Dyck, Tania Crucitti (Institute of Tropical Medicine, Antwerp, Belgium)• Laurent Belec, Ali Si-Mohammed, Jerome Legoff (Université Pierre & Marie Curie, Paris, France)• Ian MacLean (University of Manitoba, Canada)• Michael Hoelscher, Frank von Sonnenburg, Oliver Hoffmann (University of Munich, Germany)
Funding	Wellcome Trust
Dates	August 2000 – January 2004

Summary

Genital ulcers and other sexually transmitted infections (STI) have been shown to enhance the transmission of HIV infection, but many aspects of this interaction remain unclear. For example, it has been hypothesised that the prevalence and incidence of ulcers due to *Herpes simplex virus-2* (HSV-2) infection increase in mature HIV epidemics, and that HIV infected individuals with herpetic lesions excrete HIV more frequently than individuals without such lesions. It has further been suggested that the mass treatment of syphilis may lead to a paradoxical increase in HIV infection, because of an increase in the pool of individuals susceptible to syphilis. It would thus be important to investigate whether individuals treated for syphilis maintain some immunity against reinfection, and how long this may last. With respect to the control of ulcerative STI, a single dose oral treatment for syphilis that would have many advantages over the traditional treatment with penicillin injection has recently become available, but the feasibility and effectiveness of this strategy has not yet been evaluated in developing countries.

In the context of a study on HIV superinfection conducted in Mbeya, Tanzania, an opportunity has opened to address these research questions in an open cohort of 600 sex workers. Four interlinked studies are being performed: We aim to determine the prevalence and incidence of genital ulcers, and to compare the proportion of ulcers due to HSV-2 in HIV+ and HIV- individuals. The frequency of cervico-vaginal excretion of HIV in HIV infected women is being compared between women with and without HSV-2 lesions. Cohort members infected with syphilis receive treatment, and we aim to record the occurrence of and the time until reinfection. The treatment of syphilis with a single dose of oral azithromycin is being compared with standard treatment through a randomised controlled trial.

Publications

Riedner G, Rusizoka M, Hoffmann O, Nichombe F, Lyamuya E, Mmbando D, Maboko L, Hay P, **Todd J**, **Hayes R**, Hoelscher M, **Grosskurth H**.: Baseline survey of sexually transmitted infections in a cohort of female bar workers in Mbeya Region, Tanzania. *Sex Transm Infect.* 2003 Oct;79(5):382-7.

1.3 General population

Title	ORPHANS IN ZIMBABWE: THEIR INCREASED SUSCEPTIBILITY TO SEXUAL AND PHYSICAL ABUSE AND THEIR SCHOOL ACHIEVEMENT
Country	Zimbabwe
LSHTM staff	Ceilidh Staplekamp, Shabbar Jaffar
Collaborators	<ul style="list-style-type: none">• Dr Simon Gregson• Dr Geoff Foster
Funding	<ul style="list-style-type: none">• GTZ• Rotary International, Zimbabwe• Further funds being sought from Nestlé Foundation
Dates	June 2000 – May 2003

Summary

This study is currently being planned. Its aim will be to examine the plight of orphans, most of whom will have lost parents to HIV. In particular, the research will focus on whether orphans are at increased risk of sexual and physical abuse and their level of school achievement. The study will comprise about 250 orphans and about the same number of non-orphaned children.

This study is experiencing delays because of the current political situation in Zimbabwe.

Title	SOCIAL AND BEHAVIOURAL STUDIES MRC Programme on AIDS in Uganda
Country	Uganda
LSHTM staff	Brent Wolff, Jimmy Whitworth, Robert Pool, Heiner Grosskurth
Collaborators	
Funding	MRC
Dates	1989 – present

Summary

Our social science activities aim to provide a basis for subsequent descriptive and intervention studies, and also to provide rich qualitative information to supplement data already collected by larger epidemiological studies. Knowledge has been accumulated on subjects such as ways in which households and individuals cope with adversity, male and female sexual behaviour patterns, detailed investigations of sexual networks, treatment seeking behaviour for STDs, and effect of knowing HIV status on subsequent behaviour. Recently started work includes a qualitative study examining the relationship between alcohol consumption and risk of HIV infection, a study of contextual data in relation to a recently introduced nevirapine prophylaxis programme for HIV positive pregnant mothers, an investigation of the influence of HIV awareness on the process of partnership formation, adoption and maintenance of preventive behaviours within partnerships at different stages of development a study of issues of mobility and sexual health risk among out-of-school youth in two highly mobile populations from peri-urban areas and a study of HIV status disclosure in the context of two intervention trials in Entebbe. Most of this work is related to the communities involved in our epidemiological cohort studies.

Publications

Jacobs B, Kambugu FSK, **Whitworth JAG**, Ochwo M, **Pool R**, Lwanga A, Tift S, Lule J and Cutler JR. Social marketing of pre-packaged treatment for men with urethral discharge (*Clear Seven*) in Uganda. *International Journal of STD & AIDS* 2003; **14**: 216-221.

Muyinda H, Nakuya J, **Pool R** and **Whitworth J**. Harnessing the *senga* institution of adolescent sex education for the control of HIV and STDs in rural Uganda. *AIDS Care* 2003; **15**: 159-167.

*Williams A. Ageing and poverty in Africa: Uganda livelihoods in a time of HIV/AIDS. Ashgate, Aldershot, 2003 [256 pages].

Mitchell K, Nakamanya S, Kamali A and **Whitworth JAG**. Balancing rigour and acceptability: the use of HIV incidence to evaluate a community-based randomised trial in rural Uganda. *Social Science & Medicine* 2002; **54**: 1081-1091.

Mitchell K, Nakamanya S, Kamali A and **Whitworth JAG**. Exploring the community response to a randomized controlled HIV/AIDS intervention trial in rural Uganda. *AIDS Education and Prevention* 2002; **14**: 207-216.

Gysels M, **Pool R** and Nnalusiba B. Women who sell sex in a Ugandan trading town: life histories, survival strategies and risk. *Social Science & Medicine* 2002; **54**: 179-192.

Walker D, Muyinda H, Foster S, Kengeya-Kayondo J and **Whitworth J**. The quality of care by private practitioners for sexually transmitted diseases in Uganda. *Health Policy & Planning* 2001; **16**: 35-40.

Mitchell K, Nakamanya S, Kamali A and **Whitworth JAG**. Community-based HIV/AIDS education in rural Uganda: which channel is most effective? *Health Education Research* 2001; **16**: 411-423.

Morgan D, Mahe C, Okongo M, Mayanja B and **Whitworth JAG**. Genital ulceration in rural Uganda: sexual activity, treatment-seeking behavior, and the implications for HIV control. *Sexually Transmitted Diseases* 2001; **28**: 431-436.

Green G, **Pool R**, Harrison S, Hart GJ, Wilkinson J, Nyanzi S and **Whitworth JAG**. Female control of sexuality: illusion or reality? Use of vaginal products in southwest Uganda. *Social Science & Medicine* 2001; **52**: 585-598.

Nyanzi S, **Pool R** and Kinsman J. The negotiation of sexual relationships among school pupils in south-western Uganda. *AIDS Care* 2001; **13**: 83-98.

McGrath JW, Mafigiri D, Kanya M, George K, Senvevo R, Svillar G, Kabugo M and Mushiga E. Developing AIDS vaccine trials educational programs in Uganda. *Journal of AIDS* 2001; **26**: 176-181.

Gysels M, **Pool R** and Bwanika K. Truck drivers, middlemen and commercial sex workers: AIDS and the mediation of sex in south west Uganda. *AIDS Care* 2001; **13**: 373-385.

Pool R, Nyanzi S and **Whitworth JAG**. Breast feeding practices and attitudes relevant to the vertical transmission of HIV in rural south-west Uganda. *Annals of Tropical Paediatrics* 2001; **21**: 119-125.

Muyinda H, Kengeya J, **Pool R** and **Whitworth J**. Traditional sex counselling and STI/HIV prevention among young women in rural Uganda. *Culture, Health & Sexuality* 2001; **3**: 353-361.

Pool R, Nyanzi S and **Whitworth JAG**. Attitudes to voluntary counselling and testing for HIV among pregnant women in rural south-west Uganda. *AIDS Care* 2001; **13**: 605-615.

McGrath JW, George K, Svilar G, Ihler E, Mafigiri D, Kabugo M and Mugisha E. Knowledge about vaccine trials and willingness to participate in an HIV/AIDS vaccine study in the Ugandan military. *Journal of AIDS* 2001; **27**: 381-388.

Williams A and Tumwekwase G. Multiple impacts of the HIV/AIDS epidemic on the aged in rural Uganda. *Journal of Cross-Cultural Gerontology* 2001; **16**: 221-236.

Title	SEXUAL BEHAVIOUR AND PARTNERSHIP FORMATION IN THE CONTEXT OF HIV INFECTION
Countries	Tanzania, Nigeria, Burkina Faso, Zimbabwe, Jamaica, Brazil
LSHTM staff	Emma Slaymaker, Oliver Hoffman, Basia Zaba, Natalie Spark, Elizabeth Pisani, Dahlia McDaniel, John Cleland, Megan Douthwaite
Collaborators	<ul style="list-style-type: none">• Ties Boerma (WHO)• Gabriel Mwaluko, Soori Nnko (TANESA project)• Sharon Weir (Measure Evaluation, UNC)• Brent Wolff (MRC, Uganda)• Simon Gregson (Imperial College, London, UK)
Funding	<ul style="list-style-type: none">• WHO• UNAIDS• UNICEF• Measure Evaluation• EC• Wellcome Trust

Dates**Summary**

A variety of small studies have been grouped under this heading. Much of the work has to do with: describing the most suitable indicators to use to monitor changes in sexual behaviour and assessing determinants of risk behaviour, partly by means of secondary analysis of public-use data sets.

Outputs in the last two years include an assessment of the contribution of unsafe sex to the global burden of HIV disease; assistance to countries undertaking Behavioural Surveillance Surveys in the context of the UNAIDS second generation surveillance programme and contributions to the development of indicators for measuring the sexual health of young people.

We have been involved in two specialist studies of high risk behaviour: a sex worker study in Mbeya, Tanzania and a "PLACE" method study (of sites where people go to meet new sexual partners) in Jamaica.

We have investigated marriage, separation and re-marriage as risk factors for HIV infection in the Manicaland study in Zimbabwe, and shown that entry into stable partnerships is also a risk factor for HIV infection in the context of a relatively unstable marriage system. In Brazil analysis has shown that religious affiliation is closely associated with extra-marital sex in men.

An analysis of survey data in Colombia and Peru has documented trends between 1985 and 1999 in the sexual exposure and condom use of single women. Condom use rose in both countries but was more than offset by declines in virginity, thus giving rise to increased pregnancy rates and presumably increased risk of infection.

A survey conducted in Cambodia to evaluate a peer education programme aimed at unmarried youth aged 15 to 25 year olds found no significant difference in risk behaviour between intervention and control areas. The survey did find however that young men have adapted their behaviour (condom use) to the escalated risks posed by HIV/AIDS, but that with partners perceived to be low risk condom use remains low.

Publications

Slaymaker, E., Walker, N., Zaba, B. and Collumbien, M. (in press) Comparative Risk Assessment: Unsafe Sex In Comparative Quantification of Health Risks: Global and Regional Burden of Disease due to Selected Major Risk Factors. Eds. Ezzati, M., Lopez, A., Rodgers, A. and Murray, C. WHO, Geneva.

Mwaluko G, Urassa M, Isingo R, Zaba B, Boerma JT. Trends in HIV and sexual behaviour in a longitudinal study in a rural population in Tanzania, 1994-2000. Accepted for publication in AIDS, July 2003

White, R, Cleland, J and Carael, M. (2000) Links between premarital sexual behaviour and extramarital intercourse: a multi-site analysis. *AIDS*; 14 (15): 2323-2331.

Ali M. and Cleland J. (2001) The link between post-natal abstinence and extra-marital sex in Côte d'Ivoire. *Studies in Family Planning* 32 (3): 214-219.

Carael M, Ali M. and Cleland J. (2001) Nuptiality and risk behaviour in Lusaka and Kampala. *African Journal of Reproductive Health* 5 (1): 83-89

Ali MM, Cleland J, Carael M. (2001) Sexual risk behaviour in urban populations of north eastern Africa. *AIDS and Behaviour* 5(4):343-352.

Horstman R, Cleland J, Douthwaite M, Ambegaokar M, Salway S. (2002) Monitoring and evaluation of sexual and reproductive health interventions: a manual for the Reproductive Health Initiative in Asia. London School of Hygiene and Tropical Medicine and Netherlands Interdisciplinary Demographic Institute, 2002.

Ali MM, Cleland J, Shah I. (2003) Trends in reproductive behaviour among young single women in Colombia and Peru: 1985-1999. *Demography* 40(4):259-273.

Hill ZE, Cleland J, Ali M. (in press) Religious affiliation and extra-marital sex in Brazil. *International Family Planning Perspectives*.

Chapter 2 Biological Risk Factors for HIV and STI Transmission

2.1 Herpes Simplex Virus Type-2 (HSV2)

Title	MULTICENTRE INTERNATIONAL SEROEPIDEMIOLOGY STUDY OF HERPES SIMPLEX VIRUS (HSV) INFECTION (HISS STUDY)
Countries	Morocco, Brazil, Estonia, Sri Lanka, India
LSHTM staff	Philippe Mayaud
Collaborators	<ul style="list-style-type: none"> Frances Cowan, Rebecca French (Department of STDs, University College London Medical School, UK) David Brown (ERVL/CPHL)
Funding	Glaxo Wellcome, R&D Department, UK
Dates	September 1999 – December 2000 (completed)

Summary

Background

The association between Herpes Simplex Virus type 2 (HSV-2) and Human Immunodeficiency Virus (HIV) and the development of HSV vaccines have increased interest in the study of HSV epidemiology.

Objectives

To estimate the age- and gender-specific sero-prevalence of HSV-1 and HSV-2 infections in selected populations in Brazil, Estonia, India, Morocco, and Sri Lanka, countries with a relatively low HIV prevalence.

Methods

Serum samples were collected from various populations including children, antenatal clinic attenders, blood donors, hospital in-patients, and HIV-sentinel surveillance groups. STD clinic attenders were enrolled in Sri Lanka, male military personnel in Morocco. Sera were tested using a common algorithm by type-specific HSV-1 and HSV-2 antibody assay (HerpeSelect Focus California).

Results

13,986 samples were tested, 45.0% from adult females, 32.7% from adult males, and 22.3% from children. The prevalence of HSV-1 varied by site ranging from 63.1% to 92.9% in adult males and from 73.4 to 90.1% in adult females. In all countries HSV-1 seroprevalence increased significantly with age ($p < 0.001$) in both men and women.

The prevalence of HSV-2 infection varied between sites. Brazil had the highest age-specific rates of infection for both men and women, followed by Sri Lanka for men and Estonia for women, the lowest rates being found in Estonia for men and India for women respectively. In all countries, HSV-2 seroprevalence increased significantly with age ($p < 0.01$) and adult females had higher rates of infection than adult males by age of infection.

Conclusions

HSV-1 and HSV-2 seroprevalence was consistently higher in women than men, particularly for HSV-2. Population-based data on HSV-1 and HSV-2 will be useful for designing potential HSV-2 vaccination strategies and for focusing prevention efforts for HSV-1 and HSV-2 infection.

Publications

Cowan FM, French RS, **Mayaud P**, et al. Sero-epidemiological study of *Herpes simplex virus* (HSV) types 1 and 2 in Brazil, Estonia, Morocco, South India and Sri Lanka. *Sexually Transmitted Infections* 2003; **79**: 286-290.

Title	BIOLOGICAL INTERRELATIONSHIPS BETWEEN HERPES SIMPLEX VIRUS TYPE 2 (HSV-2) INFECTION AND HIV AMONG WOMEN IN BANGUI, CENTRAL AFRICAN REPUBLIC
Country	Central African Republic
LSHTM staff	Philippe Mayaud, Helen Weiss, David Mabey, Richard Hayes
Collaborators	<ul style="list-style-type: none"> • David Brown (EURL/PHLS, Colindale) • Laurent Belec (Hopital Europeen Georges Pompidou and INSERM U430, Paris, France) • Gerard Gresenguet (CNRMST, Bangui) • Francois-Xavier Mbopi-Keou (PhD student)
Funding	<ul style="list-style-type: none"> • GlaxoSmithKline (GSK), R&D Department, UK • Royal Society (RS) European Exchange grant
Dates	<ul style="list-style-type: none"> • July – November 1998 (GSK) (completed) • April 1999 – October 2001 (RS) (completed)

Summary

These series of studies combining field work at the Centre National de Reference des MST et du SIDA (CNRMST/SIDA) in Bangui (CAR) and laboratory work in two centres in London (EURL/PHLS) and Paris (HEGP and INSERM U430) formed initially part of an MSc student's summer project in 1998. The student (Francois-Xavier Mbopi-Keou) has completed a PhD programme on the genital mucosal immunity to HSV-2 and HIV.

The *aims* of the study were:

- To measure the prevalence and genital shedding of HSV-2 in a female population in Bangui (CAR);
- To determine the role of HSV2 in possible co-transmission of HIV;
- To study the correlates of HSV-2 and HIV shedding, in particular factors susceptible to influence mucosal immunity such as vitamin A and E;
- To study the genital mucosal immunity to HSV-2 and HIV.

Main results:

- The study found that the prevalences of HSV-2 antibody (91% vs. 78%, $P=0.02$), HSV-2 shedding (43% vs. 22%, $P=0.03$) and levels of HSV-2 DNA ($P=0.01$) were all significantly higher among HIV-1 seropositive women (prevalence of 15%) than among HIV-1 seronegative women. There was a significant correlation between genital HIV-1 RNA and HSV-2 DNA levels ($P=0.02$) among the 23 dually HSV-2/HIV-1 seropositive who were shedding HSV-2 DNA. This was one of the first studies suggesting that HSV-2 genital shedding may play an important role in HIV transmission in Africa.
- The lack of association between cervicovaginal HSV-2 DNA and HIV-1 DNA shedding also found in this study supports the notion that HIV-1 replication in the female genital tract may be subcompartmentalized in distinct cellular reservoirs each with their separate turnover, and which may be influenced differently under the effect of genital HSV-2 replication.
- Vitamins A and E levels were not significantly altered in HIV seropositive women, women shedding HIV-RNA or HSV2-DNA in their genital tract. However, vitamin A deficiency was associated in an additive fashion with the number of genital tract infections or serological syphilis.
- It was also demonstrated that HSV-2 shedders did not exhibit HSV2 specific mucosal immunity, whilst non-shedders have high levels of locally –produced neutralising antibodies.
- Protocols to optimise the testing of cervico-vaginal lavage samples for further shedding studies have been developed.

Publications

2003 (for earlier publications [5 papers, 5 abstracts], see previous Reports 2000, 2001, 2002)

Mbopi-Kéou F-X, Legoff J, Grésenguet G, Si-Mohamed A, Matta M, **Mayaud P**, Andréoletti L, **Weiss H**, Brown D, Malkin J-E and Bélec L. Genital shedding of HSV-2 DNA and HIV-1 RNA and proviral DNA in HIV-1- and HSV-2- co-infected African women. *Journal Acquired Immune Deficiency Syndrome* 2003; **33(2)**:121-124.

Mbopi-Kéou F.-X., Bélec L., Dalessio J., Grésenguet G., **Mayaud P.**, Corey L., Brown D.W.G., Ashley R.L. Cervicovaginal neutralizing antibodies to herpes simplex virus (HSV) in dually HSV-1- and HSV-2- seropositive women. *Clinical and Diagnostic Laboratory Immunology* 2003; **10(3)**: 388-393.

Mbopi-Keou F-X, Robinson NJ, **Mayaud P**, Belec L and DWG. Brown. Herpes simplex virus type 2 and heterosexual spread of human immunodeficiency virus infection in developing countries: hypotheses and research priorities. *Clinical Microbiology & Infection* 2003; **9 (3)**: 161-171.

Malkin J-E, **Mayaud P**, Bélec L. L'Herpes genital. Chapter in: Segondy M, et al. (eds.). *Infections virales sexuellement transmissibles*. Editions Scientifiques et Medicales Elsevier, Paris. (in press).

In preparation

Grésenguet G, **Mayaud P**, **Weiss HA**, et al. Vaginal flora changes, bacterial vaginosis and HIV-1 shedding in Bangui, Central African Republic.

In preparation

Bélec L, **Mayaud P**, **Weiss HA**, et al. Vitamin E deficiency and HIV-1 plasma load and genital shedding in women living in Central Africa.

Title	MOLECULAR EPIDEMIOLOGY OF HUMAN HERPES VIRUS 8 (HHV-8) IN AIDS ASSOCIATED KAPOSI'S SARCOMA IN BRAZIL
Country	Brazil
LSHTM staff	Philippe Mayaud, Helen Weiss
Collaborators	<ul style="list-style-type: none">• Maria Claudia Nascimento (PhD student LSHTM)• Claudio S. Pannuti (University of São Paulo Medical School, Brazil)• Chris Boshoff (University College London, UK)
Funding	PhD support for MCN obtained for 4 years – Supported by CNPq and DFID Knowledge Programme on HIV/AIDS & STIs
Dates	September 2000 – December 2004

Summary

Human herpes virus type 8 (HHV-8) and strain variants have been identified in all clinical forms of Kaposi's sarcoma (KS) (classic, endemic, iatrogenic and epidemic-or AIDS-associated). KS is the most frequent cancer associated with HIV. However, the precise routes of transmission, strain classification and epidemiology of HHV-8 (also known as Kaposi's Sarcoma-associated herpes virus, KSHV) have not been studied extensively. Given its extraordinary ethnic diversity, Brazil provides a unique opportunity to study HHV-8 strain variants in different populations.

The study will consist of a multicentre survey of prevalence of and risk factors for KSHV in three blood-donating populations in São Paulo (South-East), Manaus (North) and Salvador (North-East). The study will also try to characterise the main HHV-8 variants found in various subgroups in these separate geographical locations, from various ethnic backgrounds, with or without HIV, and with or without AIDS-KS. The study will use novel serological techniques to detect anti-HHV-8 antibodies. The genetic diversity of HHV-8 will be analysed.

Preliminary results

A molecular analysis of 83 KS biopsies from AIDS patients in São Paulo has enabled to type and classify the main circulating HHV-8 strains among AIDS patients in Southeast of Brazil. HHV-8 strains were also isolated and typed in peripheral blood of AIDS and renal transplant patients, enabling further large-scale epidemiological studies of HHV-8 using blood samples.

The multi-centre seroepidemiological study has been conducted in 2003.

An evaluation of HSV2 and KSHV serological tests is being conducted in late 2003.

Publications

Souza VAUF, Sumita LM, Freire W, Sato HK, Grandi JL, Pierrotti LC, **Nascimento MC**, Pannuti CS. Prevalence of antibodies to human herpesvirus-8 in populations with and without risk for infection in São Paulo State. *Braz J Med Biol Res* 2003; 36: (in press).

Nascimento MC, Wilder N, Pannuti CS, **Weiss H**, **Mayaud P**. Molecular characterization of Kaposi's sarcoma associated herpesvirus (KSHV) from AIDS patients in São Paulo, Brazil. *Journal of General Virology* (submitted).

Title	THE ASSOCIATION BETWEEN HSV-2 AND HIV-1 INFECTIONS AMONG THAI HOSPITAL PATIENTS
Country	Thailand
LSHTM staff	Shabbar Jaffar
Collaborators	Sukhum Jiamton, Puan Suthipinittharm (Mahidol University, Bangkok, Thailand)
Funding	GlaxoSmithKline
Dates	January 2000 – April 2004

Summary

The aim of this study was to examine whether *Herpes simplex* virus type-2 infection leads to a greater level of HIV-1 genital shedding. Approximately 140 HSV-2 seropositive, some of whom had a HSV-2 genital ulcer, some of whom were HSV-2 positive but did not have an ulcer and some of whom were HSV-2 negative were recruited. Analysis will examine rates of HIV genital shedding in these groups, taking clinical stage into account.

Approximately 20 HIV-1 infected patients with genital ulcers, half women and half men, were also followed longitudinally. The changes in genital shedding of HIV following healing of the ulcer, taking clinical stage into account, will be examined in these patients.

Title	CLINICAL EPIDEMIOLOGY OF HSV-2 AND THE IMPACT OF HSV SUPPRESSIVE THERAPY TO REDUCE HIV INCIDENCE IN HIGH RISK WOMEN, TANZANIA
Country	Tanzania
LSHTM staff	Deborah Watson-Jones, Richard Hayes, Helen Weiss, David Ross, Tim Clayton, Tamara Hurst, Dean Everett, Tobias Chirwa
Collaborators	<ul style="list-style-type: none">• African Medical & Research Foundation (AMREF), Mwanza, Tanzania• National Institute of Medical Research (NIMR), Mwanza, Tanzania• Regional Medical Office, Mwanza, Tanzania• Institute of Tropical Medicine (ITM), Antwerp, Belgium• Hôpital Européen Georges Pompidou, Université Pierre & Marie Curie (Paris VI), Paris, France• University College Hospital, London, UK• Kahama Mining Corporation Ltd., Geita Gold Mine, Tanzania• University of Laval, Quebec, Canada
Funding	Wellcome Trust
Dates	November 2002 – October 2006

Summary

Objectives

1. To determine the current aetiology of genital ulceration in NW Tanzania;
2. To determine whether HSV-2 suppressive therapy will reduce the incidence of HIV in women at high risk of acquiring HIV;
3. To examine the interaction between HIV and HSV-2 shedding and the effect of HSV suppressive therapy on HIV and HSV viral shedding in high risk women (HRW).

Methodology

Aetiology of genital ulcers will be measured in STI clinic attenders presenting with symptomatic genital ulceration in Mwanza.

A placebo-controlled trial of HSV-2 suppressive therapy with aciclovir, as a strategy to reduce HIV incidence, HSV-2 and HIV viral shedding, will be carried out in a cohort of 900 HRW in communities neighbouring large-scale goldmines or along major truck routes.

The interaction between HIV and HSV-2 shedding will be examined in a sub-group of HRW from the cohort.

Results

The aciclovir and placebo tablets have been manufactured. Preliminary fieldwork started in May 2003 with mapping of bars, guesthouses and other facilities in 13 high transmission areas (HTA) in Mwanza and Shinyanga Regions, NW Tanzania. Screening of HRW working in 8 of these HTA for HSV infection began in November 2003. Enrolment to the main trial will start in January 2004.

2.2 Bacterial vaginosis (BV) and vaginal infections

Title	EVALUATION OF VARIOUS METHODS FOR THE DIAGNOSIS OF BACTERIAL VAGINOSIS IN GAMBIAN WOMEN
Country	the Gambia
LSHTM staff	Philippe Mayaud, Linda Morison
Collaborators	Edward Demba, Beryl West, Maarten Schim van der Loeff, Akum Aveika, Robin Bailey (MRC Laboratories, Fajara, the Gambia)
Funding	<ul style="list-style-type: none"> • WHO - STI programme • Litmus concepts, USA (donation of survey materials and tests)
Dates	March 2000 – July 2001 (completed)

Summary

The study's aims were to:

- Evaluate the WHO algorithm for management of vaginal discharge among symptomatic women presenting with vaginal discharge to an urban STD clinic in Fajara;
- Obtain detailed microbial evaluation of vaginal flora and of various diagnostic procedures for bacterial vaginosis;
- Evaluate a new rapid diagnostic kit (FemExam®, Litmus, USA) for bacterial vaginosis among symptomatic women attending an STI/GUM clinic;
- Measure cure rates following syndromic treatment.

Main results

The prevalence of bacterial vaginosis in the women attending the GUM clinic with vaginal discharge symptoms was 49%. Diagnosis using Amsel's clinical criteria was 78% sensitive but only 58% specific and resulted in a 21% over treatment rate. Using either FemExam® Card 1 or Card 2 singly the sensitivities were similar, around 70% but with a higher specificity on Card 2 (81%). Either card resulted in similar over treatment rates. The best sensitivity (91%) was obtained using cards 1 and 2 combined but this led to more false positives and lower specificity. Using one FemExam® card is the best choice cost wise being cheaper than using Amsel's criteria. Using the two-card system at the proposed lower \$1price also becomes more feasible.

Publications

West B, **Morison L**, Schim van der Loeff M, Gooding E, Aveika A, Demba E, **Mayaud P**. Evaluation of a new diagnostic kit for bacterial vaginosis in patients with vaginal discharge in the Gambia. *Sexually Transmitted Diseases* 2003; **30(6)**: 483-489.

In preparation

West B, **Morison L**, **Mayaud P**, et al. Evaluation of the female genital discharge syndrome algorithm in the Gambia.

Title	EVALUATION OF IMMUNO-PATHOLOGICAL EFFECTS OF BACTERIAL VAGINOSIS AND VAGINAL FLORA CHANGES IN GAMBIAN WOMEN
Country	the Gambia
LSHTM staff	Philippe Mayaud, Linda Morison
Collaborators	Edward Demba, Beryl West, Maarten Schim van der Loeff, Akum Aveika, Robin Bailey (MRC Laboratories, Fajara, the Gambia)
Funding	MRC Laboratories, the Gambia
Dates	2001 – present (part-time PhD with Open University)

Summary

The first part of the project is linked to the project titled “*Evaluation of various methods for the diagnostic of bacterial vaginosis in Gambian women*”, aimed at defining the prevalence of BV in Gambian women attending a GUM clinic, and will establish the necessary methodology for determination of vaginal bacterial ecology, including appropriate culture systems and the use of molecular diagnostic techniques.

The second part of the project will aim at further characterising vaginal flora and BV in various populations (with/without symptoms, urban/rural, pregnant/non-pregnant) and better understand the immunopathological processes involved in BV through, e.g.:

- Typing Lactobacilli strains;
- Evaluating chemical composition of vaginal flora;
- Evaluating the role of sperm on vaginal ecology;
- Measuring levels of cytokines and quantitation of lactoferrin.

Main results/outputs

Successful systems for the growth of aerobic and anaerobic flora have been established in the lab, and a first study looking at prevalence of BV and vaginal flora changes in symptomatic women has been conducted and results reported in international STI conferences and in publications.

A number of laboratory experiments have been undertaken. Firstly, a study assessing the role of pH modification and human sperm on growth of various BV-associated organisms confirmed previous research highlighting that *Lactobacilli spp* are generally associated with lower pH values while BV-associated bacteria grow better in pH closer to pH 7.0. The experiment also shows that BV-associated bacteria are very sensitive to $\text{pH} \leq 4.5$, thus suggesting a possible mechanism for intervention using vaginal pH lowering compounds.

Secondly, a pilot study assessed the expression of inflammatory cytokines (TNF alpha and IL-beta, others such as IL-6 and IL-10 will follow) in vaginal washings of symptomatic women seen at the GUM clinic: higher levels of these cytokines were found among women with BV (by Gram stain), which is interesting since BV was believed hitherto to be a non-inflammatory condition. These experiments will now be carried out in larger numbers and with vaginal cultures as additional endpoints to assess the relationship of cytokines with vaginal microflora. Finally, a study will be conducted to elicit the presence of Lactobacilli phages among women with or without BV. The presence of these phages has been suggested as a potential mechanism for the establishment of BV.

These pathophysiological studies of vaginal flora aim to better inform patient management strategies.

Publications

Demba E, Schim van der Loeff M, Aveika A, Gooding E, Bailey R, **Mayaud P**, West B. Bacterial vaginosis and vaginal flora patterns in women presenting with vaginal discharge syndrome in The Gambia. *Journal of Clinical Microbiology* (submitted).

Title	EVALUATION OF A DIAGNOSTIC TESTS FOR BACTERIAL VAGINOSIS IN A COHORT OF RURAL GAMBIAN WOMEN
Country	the Gambia
LSHTM staff	Philippe Mayaud, Linda Morison
Collaborators	<ul style="list-style-type: none"> • Gijs Walraven, Beryl West, Edward Demba (MRC Laboratories, Farafenni and Fajara, the Gambia) • Kurt Cook (MSc student, LSHTM)
Funding	<ul style="list-style-type: none"> • Litmus Concepts Inc., USA (donation of survey materials) • LSHTM (support to an MSc student)
Dates	March – July 1999 (completed)

Summary

Evaluation of a new rapid diagnostic kit (FemExam®, Litmus, USA) for bacterial vaginosis in women, consisting of cards to detect amines and measure pH (card 1) and *Gardnerella vaginalis* (card2).

The project was conducted by an MSc Student (Kurt Cook) for his summer project nested within a larger reproductive morbidity survey (RMS) in rural Gambia.

Main results:

- The prevalence of BV prevalence was 38% by Nugent's (gram stain) criteria, and similar among women reporting and not reporting a symptom of vaginal discharge.
- When compared with Gram stain criteria, Amsel's clinical criteria had a sensitivity of 39.1% and specificity of 94.2%.
- Various combinations of the three individual FemExam® tests (card 1 for pH and amine test, or card 2 for *Gardnerella vaginalis* PIP test) gave sensitivities ranging from 44.5% to 65.4% and specificities ranging from 76.9% to 90.0%.
- Cost per patient and per true case ranged from \$0.69 and \$1.82 respectively for Gram stain diagnosis to \$8.09 and \$21.29 for FemExam® 2 card method.
- The FemExam® test compared favourably with conventional clinical diagnosis and has the advantage of being rapid, less subjective and easily performed in clinical settings of resource-poor countries. Cutting its cost would provide wider accessibility in developing countries.

Publications*In preparation*

Cook K, Demba E, West B, Ekpo G, Scherf C, **Morison L**, Walraven G, **Mayaud P**. Rapid diagnostic test and other screening options for bacterial vaginosis in rural Gambian women.

Conferences (for past presentations, see Report 2001)

Title	THE AETIOLOGY OF STI SYNDROMES AND EVALUATION OF TREATMENT ALGORITHMS IN MASAKA DISTRICT, UGANDA
Country	Uganda
LSHTM staff	Philippe Mayaud, Jimmy Whitworth
Collaborators	<ul style="list-style-type: none"> Anatoli Kamali, Peter Hughes, Dilys Morgan, Jimmy Whitworth (MRC Programme on AIDS, Entebbe, Uganda) Ian Maclean (University of Manitoba, Canada)
Funding	MRC Programme on AIDS, Uganda
Dates	January 2000 – June 2001 (completed)

Summary

Evaluation of the microbial aetiologies and validity and costs of the main STI syndromes in 3 rural health units in the Masaka District. This research supports the main Masaka community STD trial.

Main results/outputs

- Urethral discharge syndrome (N=166): the main pathogen was *N gonorrhoeae* (NG, 57% by urethral culture, 70% by LCR on a urine specimen) and *C trachomatis* (CT) was found in 10%. 6% of men had a positive *T vaginalis* culture (often in association with NG).
- Vaginal discharge syndrome: most frequent were vaginitis-causing agents such as *T vaginalis* (28%), *C albicans* (27%) or bacterial vaginosis (48%); agents causing cervicitis were rarely found, NG (9.4%) and CT (<1%).
- Genital ulcer syndrome: using a multiplex PCR method, the study found that HSV-2 was the most prevalent STI pathogen (50%). *Haemophilus ducreyi* and *Treponema pallidum* were rarely found (around 3% each). 12% of ulcers yielded pure growths of Staphylococci or Streptococci on culture in the absence of an organism on PCR. However, these micro-organisms could be secondary contaminants to the genital wound, rather than aetiological agents.

Broadly, the study supports the syndromic approach for male and female discharge syndromes, TV treatment may be added to the M-GDS algorithm. The study also confirms that HSV has become the number one pathogen in GUS. Antibiotic treatment targeting bacterial infections is unlikely to be beneficial (although it may help with secondary bacterial infections). Algorithms should be revised to include specific anti-herpes therapy for genital ulcers.

Publications

Presentation at WHO STI Guidelines working group, Geneva, November 2001.

Kasse M, Pickering J, Van Der Paal L, Hughes P, **Mayaud P, Whitworth J**. The aetiology of sexually transmitted infections in rural South-west Uganda.

Abstract. 13th International Conference on AIDS and STD in Africa (ICASA), Kenya, September 2003.

In preparation

Pickering JM, **Whitworth JAG**, Hughes P, Kasse M, Morgan D, Mayanja B, Van der Paal L, **Mayaud P**. Aetiologies of STI syndromes and response to syndromic management in the context of an STI intervention trial in Masaka, Uganda.

In preparation

Manuscripts on evaluation and cost-effectiveness of the guidelines.

Title	THE EPIDEMIOLOGY OF TRICHOMONAS VAGINALIS AND RELATED INFECTIONS
Country	Ghana
LSHTM staff	David Mabey, Helen Weiss
Collaborators	<ul style="list-style-type: none">• Yaw Adu-Sarkodie (Komfo Anokye Teaching Hospital, Kumasi, Ghana)• Anne Buvé, Tania Crucitti (Institute for Tropical Medicine, Antwerp, Belgium)
Funding	<ul style="list-style-type: none">• Association of Commonwealth Universities• DFID
Dates	2001 – 2004

Summary

We are studying the prevalence of and risk factors for vaginal, rectal and oral infections with *T. vaginalis* and the morphologically indential protozoal parasites *Pentatrichomonas hominis* and *Trichomonas tenax* in pregnant women, using a newly developed species specific polymerase chain reaction (PCR) assay. We are also comparing PCR with traditional diagnostic tests including microscopy, culture and antigen detection assays, and assessing the prevalence of *T. vaginalis* strains resistand to nitro imidazoles and their contribution to failure of standard treatment with metronidazole.

2.3 Syphilis

Title	IMPACT OF SYPHILIS ON PREGNANCY OUTCOME AND EVALUATION OF SYPHILIS SCREENING STRATEGIES TO REDUCE ADVERSE PREGNANCY OUTCOMES IN MWANZA, TANZANIA
Country	Tanzania
LSHTM staff	Deborah Watson-Jones, David Mabey, Richard Hayes, Helen Weiss, David Ross, James Todd (ITD); Lilani Kumaranayake, Fern Terris-Prestholt (PHP)
Collaborators	<ul style="list-style-type: none"> • National Institute of Medical Research (NIMR), Mwanza, Tanzania • Regional Medical Office, Mwanza, Tanzania • Bugando Medical Centre, Mwanza, Tanzania • Sengerema Designated District Hospital, Tanzania • Institute of Tropical Medicine, Antwerp, Belgium • Universities of Montreal and Quebec, Canada • University of Newcastle, UK
Funding	Wellcome Trust
Dates	1997 – 2001

Summary

Objectives

1. To measure the impact of untreated maternal syphilis on pregnancy outcome;
2. To measure the effectiveness and cost-effectiveness of antenatal syphilis screening to prevent adverse birth outcomes.

Methodology

1. Retrospective cohort study;
2. Prospective cohort study of pregnant women.

Results

1. 49% of women with untreated high titre syphilis had a stillbirth or LWB infant. In unscreened women, 51% of stillbirths, 24% of preterm livebirths and 17% of all adverse pregnancy outcomes were attributable to maternal syphilis.
2. There was no increased risk for adverse pregnancy outcome for women treated for high titer active syphilis with single dose benzathine penicillin 2.4 MU IM. (OR 0.76, 95% CI 0.4-1.4) or low titer active syphilis (OR 0.95, 95% CI 0.6-1.5) compared to seronegative women. Syphilis screening and treatment cost \$10.56 per DALY, comparable to interventions for the prevention of MTCT of HIV.

Publications

Watson-Jones D, Chungalucha J, Gumodoka B, **Weiss H**, Rusizoka M, Ndeki L, Whitehouse A, Balira R, **Todd J**, Ngeleja D, **Ross D**, Buvé A, **Hayes R**, **Mabey D**. Syphilis in Pregnancy in Tanzania I. Impact of maternal syphilis on outcome of pregnancy. *Journal of Infectious Diseases* 2002;186: 940-7.

Watson-Jones D, Gumodoka B, **Weiss H**, Chungalucha J, **Todd J**, Mugeye K, Buvé A, Kanga Z, Ndeki L, Rusizoka M, **Ross D**, Marealle J, Balira R, **Mabey D**, **Hayes R**. Syphilis in pregnancy in Tanzania II. The effectiveness of antenatal syphilis screening and single dose benzathine penicillin treatment for the prevention of adverse pregnancy outcomes. *Journal of Infectious Diseases* 2002;186: 948-57.

Terris-Prestholt F, **Watson-Jones D**, Mugeye K, Kumaranayake L, Ndeki L, **Weiss H**, Chungalucha J, **Todd J**, Lisekie F, Gumodoka B, **Mabey D**, **Hayes R**. Is antenatal syphilis screening still cost-effective in sub-Saharan Africa? *Sexually Transmitted Infections* 2003; 79:375-81.

In preparation

Antenatal Syphilis Screening in sub-Saharan Africa – Lessons Learnt from Tanzania.. **Watson-Jones D**, Oliff M, **Terris-Prestholt F**, Chungalucha J, Gumodoka B, Mayaud P, Semakafu AM, Kumaranayake L, Gavyole A, **Mabey D**, **Hayes R**.

2.4 HIV and associated infections

Title **THE NATURAL HISTORY OF HIV-1, HIV-2 AND DUAL INFECTIONS IN WEST AFRICA**

Country

LSHTM staff Shabbar Jaffar

Collaborators Hilton Whittle *et al*, MRC laboratories, Fajara, the Gambia.

Funding MRC

Dates September 1999 – April 2004

Summary

This study examined the rates of survival of HIV-1, HIV-2 and dually infected individuals, and the factors that predicted survival, including CD4 cell count and plasma viral load. Studies were conducted among hospital patients and among individuals living in a rural community. The studies have been completed and the data are currently being written up for publication.

This work has produced a PhD thesis, 2 papers (one published and one submitted listed below) and a further 2 papers are currently underway, one is an overview of the natural history of HIV-1, HIV-2 and dual infections in sub-Saharan Africa and the other, which is shorter, is the ability of simple and cheap surrogate markers in predicting clinical outcome among HIV-2 infected individuals.

Publications

Abraham S. Alabi, **Shabbar Jaffar**, Koya Ariyoshi, Tom Blanchard, Maarten Schim van der Loeff, Akum Aveika Awasana, Tumani Corrah, Sehu Sabally, Ramu Sarge-Njie, Fatim Cham-Jallow, Assan Jaye, Neil Berry and Hilton Whittle. Plasma viral load, CD4 % and survival of HIV-1, HIV-2, and dually infected Gambian patients. *AIDS* 2003; 17: 1513-20.

Jaffar S, Grant A, Whitworth J, Smith PG and Whittle H. The natural history of HIV-1, HIV-2 and dual infections in sub-Saharan Africa (*Bulletin WHO*) (in press).

Schim van der Loeff MF, **Jaffar S**, Aveika AA, Sabally S, Corrah T, Harding E, Alabi A, Bayang A, Ariyoshi K, Whittle HC. Mortality of HIV-1, HIV-2 and HIV-1/HIV-2 dually infected patients in a clinic-based cohort in The Gambia. *AIDS*. 2002; 16:1775-83.

Jaffar S, The natural history of HIV-1, HIV-2 and dual infections. PhD Thesis, Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, 2001.

In preparation

Jaffar S, Whittle HC et al. The prognostic value of the plasma level of soluble urokinase plasminogen activator receptor, CD4 count, plasma viral load and other markers in predicting clinical outcome in HIV-2 infected individuals (for *AIDS*).

Title	EPIDEMIOLOGY OF HUMAN PAPILLOMA VIRUS (HPV) INFECTION AND CERVICAL DYSPLASIA IN TANZANIA
Country	Tanzania
LSHTM staff	Philippe Mayaud, David Mabey, Helen Weiss, Richard Hayes
Collaborators	<ul style="list-style-type: none">• David Ross, John Chagalucha (NIMR/MEMA project Mwanza, Tanzania)• Charles Lacey, Dilbert Gill (St Mary's Hospital, London, UK)• Michael Hagensee (University of Louisiana, USA)
Funding	DFID Knowledge Programme on HIV/AIDS & STI
Dates	2001 – 2003

Summary*Rationale and Methodology*

Human papillomaviruses (HPV) are among of the most prevalent STI pathogens worldwide. High-risk oncogenic genital HPV (HR-HPV) have been shown to be the causative agents of cervical cancer and pre-cancer or squamous intra-epithelial lesions (SIL), which is the most common female cancer in sub-Saharan Africa, with age-standardised incidence rates being fourfold higher in Africa than in North America and Europe. However, detailed data on HPV epidemiology, strain distribution and natural history are scarce from African countries. The influence of HIV on the natural history of HPV and SIL is not well documented in Africa.

Objectives

The objectives of this project, which draws on previously collected samples in the Mwanza region, are:

1. To determine the prevalence, risk factors, strain characteristics of HPV infection among pregnant women in urban Mwanza;
2. To compare the prevalence of HPV 16 (most common oncogenic type) using serology and PCR test on cervical samples;
3. (If HPV-16 appears useful) to determine the prevalence and incidence of HPV-16 in a cohort of young people living in rural areas of Mwanza, and correlate with HIV acquisition and study site (MEMA intervention or comparison).

Main outcomes

A 34% cervical HPV prevalence was found among 561 pregnant women in Tanzania, and 84% of typeable samples were high-risk oncogenic HPV strains. Rates of HIV (15%), other STI/RTI (80%) and SIL (7%; high-grade SIL, 3%) were high in this supposedly low-risk population. HPV infection was associated with some behavioural factors (short duration of relationship, single status, not using condoms) and gonorrhoea, but there was no overall association between HPV and HIV, except an association of HR-HPV strains in the younger and older groups of women (aged 15-19, and >30, respectively). This may be due to confounding by behaviour in the young group, but also suggest that the principal HIV/HPV interaction in this population is for HIV to upregulate HPV persistence, leading to subsequent development of high-grade SIL.

HPV-16 was the most prevalent subtype among HPV-infected women (18%) and among women with cervical neoplasia (16%). Contrary to findings in industrialised countries, where HPV vaccines development targets few HPV strains (mainly HPV-16 and -18), a multivalent HPV (16,18,31,33,35) vaccine would be necessary to prevent 50% of neoplasia in this population. HPV strains 6 and 11 were associated with genital warts.

Testing with HPV 16 serology (and novel serologies for HPV 6/11 and 18) took place in 2003. Analysis is ongoing.

Publications

Mayaud P, Gill DK, **Weiss HA**, et al. The interrelationships of HIV, cervical human papillomavirus and neoplasia, among antenatal clinic attenders in Tanzania. *Sexually Transmitted Infections* 2001; **77**: 248-254.

Mayaud P, **Weiss HA**, Lacey CJN, Gill DK, **Mabey DCW**. Genital human papillomavirus genotypes in northwestern Tanzania. *Journal of Clinical Microbiology* 2003; **Sept**: 4451-3.

Title	EPIDEMIOLOGY OF HUMAN PAPILLOMA VIRUS (HPV) INFECTION AND CERVICAL DYSPLASIA IN BURKINA FASO
Country	Burkina Faso
LSHTM staff	Philippe Mayaud, Helen Weiss
Collaborators	<ul style="list-style-type: none"> Nicolas Nagot, PhD student, LSHTM (Centre Muraz, Bobo Dioulasso, Burkina Faso) Philippe van de Perre, Michel Segondy (Department of Microbiology, University of Montpellier, France)
Funding	<ul style="list-style-type: none"> Agence Nationale de Recherche sur le SIDA (ANRS), France Unité Mixte de Recherche U36, Montpellier, France DFID Knowledge Programme on HIV/AIDS & STIs
Dates	2003 – 2006

Summary*Rationale and Methodology*

Human papillomaviruses (HPV) are among of the most prevalent STI pathogens worldwide. High-risk oncogenic genital HPV (HR-HPV) have been shown to be the causative agents of cervical cancer and pre-cancer or squamous intra-epithelial lesions (SIL), which is the most common female cancer in sub-Saharan Africa, with age-standardised incidence rates being fourfold higher in Africa than in North America and Europe. However, detailed data on HPV epidemiology, strain distribution and natural history are scarce from African countries. The influence of HIV on the natural history of HPV and SIL is not well documented in Africa.

Objectives

The objectives of this project are:

- To determine the prevalence, incidence, risk factors, strain characteristics of HPV infection, and SIL, in a cohort sex workers in Bobo Dioulasso, Burkina Faso;
- To determine factors associated with persistence of HR-HPV and high-grade SIL, and relate to HIV and immunological serostatus of the women;
- To evaluate the performance of alternative techniques for sequencing and phylogenetic analyses of HPV strains;
- To determine the impact of ARV on the natural history of HPV and SIL.

Main outcomes

The project has started in 2003 with a baseline cross-sectional study of HPV, SIL and immunological status of FSW in Bobo Dioulasso.

Title *Antenatal clinic and population-based HIV surveillance in Northern Malawi*

Country Malawi

LSHTM staff Paul Fine, Mia Crampin, Andreas Jahn, Judith Glynn, Basia Zaba, Joanne Hemmings

Collaborators

- Dr Bagrey Ngwira, Dr Frank Mwaungulu (Karonga Prevention Study, Malawi)
- National AIDS Control Programme, Malawi

Funding Wellcome Trust

Dates

Summary

Objectives

- Assess accuracy of ANC surveillance;
- Monitor trends in HIV prevalence;
- Measure inter-relationships between HIV and fertility.

Methodology

As part of the Karonga Prevention Study in Northern Malawi, we are carrying out antenatal clinic (ANC) HIV surveillance, in conjunction with the National AIDS Control Programme. HIV prevalence estimates in ANCs are compared with community HIV prevalence from case control studies in the district.

ANC surveillance continues, but with modifications to the data collection instruments to allow for the investigation of proximate determinants of fertility (contraceptive use, foetal losses, lactational amenorrhea and marital history). Women who do not attend ANC clinics are identified in a community census and compared with those attending ANCs with respect to HIV status and proximate determinants of fertility. In depth, qualitative interviews are planned with a small sample of women identified as possibly suffering from primary or secondary infertility to elucidate the effects of this on their partnership formation patterns.

Named testing and Nevirapine for prevention of mother-to-child transmission has been introduced in one clinic so far. HIV prevalence trends based on named testing will be compared to earlier results based on anonymous testing, and background characteristics of women agreeing to be tested will be monitored.

Results

Age, sex and area-standardized HIV prevalence in women aged 15-49 in the population was 3.9% in 1988-90, 12.5% in 1991-1993 and 13.9% in 1998-2001. For men, HIV prevalence was 3.7%, 9.2% and 11.4% in the same periods. The age and area adjusted HIV prevalence in the ANC in 1999-2001 was 9.2%. The underestimate can be largely explained by reduced fertility in HIV-positives, which was demonstrated in both ANC and community populations. A previously recommended parity-based adjustment gave an estimated HIV prevalence of 15.0%.

Publications

Crampin AC, Glynn JR, Ngwira BMM, Mwaungulu FD, Pönnighaus JP, Warndorff DK, Fine PEM. Trends and measurement of HIV prevalence in northern Malawi, 1988-2001 *AIDS* 2003;17:1817-25

Title	HIV SUBTYPES AND HISTORY OF THE HIV EPIDEMIC IN NORTHERN MALAWI
Country	Malawi
LSHTM staff	Paul Fine, Judith Glynn, Philip Broadbent, Keith Branson, Mia Crampin
Collaborators	<ul style="list-style-type: none"> • Dr Grace McCormack (National University of Ireland, Maynooth) • Dr Jonathan Clewley (HPA)
Funding	Wellcome Trust
Dates	

Summary

Objectives

To characterise the early evolution and spread of HIV in Northern Malawi.

Methods

As part of the Karonga Prevention Study in Northern Malawi, blood samples were collected on filter papers in 1981-84 and 1987-89 from all individuals (more than 44,000) living in two areas of Karonga District, northern Malawi. The samples included 203 that were HIV-1 positive. We undertook a phylogenetic analysis of DNA sequences of the *env* and/or *gag* genes from all those from whom appropriate templates could be amplified (179).

Results

The first 4 HIV positive specimens were from 1982: one A, one D and two unclassifiable, possibly a new C sub-subtype. Of the 11 positive specimens from 1982-84, 6 (55%) were subtype C. By 1987-89, 152/168 (90%) of sequences were subtype C ($p=0.004$ compared with earlier period). Others were subtypes A (3) and D (6), AC (2), AD and DC recombinants, and the unclassifiable clade (3). The non-C subtypes were more common in the north of the district, near the Tanzanian border, where the first A and D specimens were seen. The subtype C specimens included clusters of closely related strains, indicating local spread, and more distantly related strains, indicating multiple introductions. Four of the early subtype C sequences were closely related and were found at the base of a large clade of low diversity that accounted for 40% of C sequences in the late 1980s.

This shows a significant increase in subtype C as a proportion of HIV subtypes in this area during the 1980s. This greater success of C, and the extensive spread of a single clade, could be due to a founder effect and/or to biological differences in transmissibility.

Further studies will look at more recent specimens and changes over time in individuals.

The specimens from the early 1980s are among the earliest in existence, including the earliest sequence of subtype C. They are being explored further to investigate the origins of the HIV and subtype C epidemic.

Publications

McCormack GP, **Glynn JR**, **Crampin AC**, Sibande F, Mulawa D, Fine PEM, Clewley JP. Highly divergent HIV-1 group M sequences evident in Karonga District, Malawi in the early 1980s. *AIDS Research and Human Retroviruses* 2003;19:441-5

McCormack GP, **Glynn JR**, **Crampin AC**, Sibande F, Mulawa D, Bliss L, Broadbent P, Abarca K, Pönnighaus JM, Fine PEM, Clewley JP. Emergence and early evolution of the HIV-1 subtype C epidemic in rural Malawi. *Journal of Virology* 2002;76:12890-9.

Title	GENETIC EPIDEMIOLOGY OF MYCOBACTERIAL AND HIV INFECTIONS IN NORTHERN MALAWI
Country	Malawi
LSHTM staff	Paul Fine, Hazel Dockrell, Sian Floyd, Lyn Bliss, Keith Branson, Gillian Black, Mia Crampin
Collaborators	Professor Adrian Hill, Dr Jodene Fitness (Oxford)
Funding	Wellcome Trust

Dates**Summary**

As part of the Karonga Prevention Study in Northern Malawi, host genetic relationships with HIV-associated and non HIV-associated tuberculosis are being examined. Total gene scans will be used in related individuals identified from the database, and associations with candidate genes are being evaluated in case-control studies. Separate studies explore correlates of immunological and genetic determinants of natural and vaccine-derived immunity.

Title	THE EFFECT OF HIV ON MORBIDITY AND MORTALITY IN SOUTH AFRICAN GOLD MINERS
Country	South Africa
LSHTM staff	Pam Sonnenberg, Judith Glynn
Collaborators	<ul style="list-style-type: none">• Jill Murray (National Institute for Occupational Health, and University of Witwatersrand, Johannesburg, South Africa)• Stuart Shearer, André Bester (Gold Fields Ltd)
Funding	Colt Foundation
Dates	2002 – 2004

Summary*Objectives*

Assess impact of HIV infection on morbidity, mortality and health service use, by time since infection.

Methodology

Retrospective cohort study of miners with known dates of seroconversion to HIV.

The project aims to assess mortality and morbidity in miners with known dates of seroconversion to HIV infection (n=1950) and compare them with miners who are known to be HIV negative (n=6243). Follow-up is up to 10 years.

At present, follow-up data are being obtained from several sources.

Results

Not yet available.

Title	BASIC SCIENCE STUDIES MRC Programme on AIDS in Uganda
Country	Uganda
LSHTM staff	Pontiano Kaleebu, Jimmy Whitworth, Frances Gotch, Heiner Grosskurth
Collaborators	<ul style="list-style-type: none">• Centre for HIV Research, Edinburgh, UK• Central Public Health Laboratory, Colindale, UK• Chelsea and Westminster Hospital, London, UK• St Mary's Hospital, London, UK• University of Washington, Seattle, USA
Funding	<ul style="list-style-type: none">• MRC• Wellcome Trust• NIH
Dates	1994 – present

Summary

Many of our basic science laboratory studies are conducted in a Category 3 containment suite in Entebbe refurbished by MRC in 1995 where we focus on HIV isolation and characterization, viral co-receptor usage and viral neutralisation assays. Our facilities also include flow cytometers and a scintillation counter allowing us to carry out cellular immunology studies such as intracellular cytokine staining and proliferation assays. Further funding from the Wellcome Trust has allowed us to expand our laboratory facilities and to undertake more studies to look at dendritic cell function in HIV infected individuals and at cross clade CTL responses using ELISPOT assays and intracellular cytokine staining. We also conduct studies examining the interactions between HIV and tuberculosis and HIV and helminth infections using different cytokine assays. For some time we have worked on various molecular and serological assays to subtype HIV-1. We have developed a subtyping protocol which correctly identifies 95% of isolates at 20% of the cost of DNA sequencing (which is the standard method, but not available in Uganda). Using this protocol we have found that HIV-1 subtypes A and D predominate in our study populations. A very similar protocol for subtyping HIV-1 has now been adopted in the United Kingdom.

Our laboratory studies focus on virology, cellular immunology and subtyping methods suitable in the Ugandan context. The work is designed to promote understanding the transmission and pathogenesis of HIV, its interactions with other diseases and to contribute towards the development of a vaccine suitable for Uganda. We were collaborators in the recently completed ALVAC phase I HIV vaccine trial, the first to be conducted in Africa. In 2000 IAVI entered a partnership with the Ugandan Ministry of Health at UVRI for the development and testing of preventive HIV vaccines in Uganda. We are actively involved in this partnership, and Dr Pontiano Kaleebu, who is the head of our basic sciences section, is also leading these IAVI studies.

The laboratory work is based on samples from our large well-characterised longitudinal cohorts, which have been followed now for more than 10 years. Recently we have also established cohorts of highly exposed but seronegative individuals and mother and child pairs. Dr David Yirrell, who is based at the Centre for HIV Research in Edinburgh, is a member of the Programme staff who conducts most of our sequencing work. In addition we have active collaborative links with the Central Public Health Laboratory (Colindale, UK), Professor Frances Gotch's group at Chelsea and Westminster Hospital (London), Professor Jon Weber's group at St Mary's Hospital (London), and Professor Jim Mullin's group at the University of Washington (Seattle, USA).

Publications

Kaleebu P, Ross A, Morgan D, Yirrell D, Oram J, Rutebemberwa A, Lyagoba F, Hamilton L, Biryahwaho B and **Whitworth J**. Relationship between HIV-1 Env subtypes A and D and disease progression in a rural Ugandan cohort. *AIDS* 2001; 15: 293-299.

Morgan D, **Kaleebu P, Whitworth J**, Yirrell D, Rutebemberwa A, Shier R, Sebabi B, Gilmour J, Eotu H, Omoding N and **Gotch F**. The stability between two HIV-1 RNA levels measurements one year apart and the relationship with HIV subtype in rural Uganda. *International Journal of STDs & AIDS* 2001;12: 116-121.

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Mugerwa RD, **Kaleebu P**, Mugenyi P, Katongole-Mbidde E, Hom DL, Byaruhanga R, Salata RA, Ellner JJ and the HIV-1 Vaccine Trial Group. First trial of the HIV-1 vaccine in Africa: Ugandan experience. *British Medical Journal* 2002; 324: 226-229.

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Tchilian EZ, Dawes R, Ramaley PA, **Whitworth JA**, Yuldasheva N, Wells RS, Watera C, French N, Gilks CF, Kunachiwa W, Ruzibakiev R, Leetrakool N, Carrington CVF, Ramdath DD, **Gotch F**, Stephens HA, Hill AV and Beverley PCL. A CD45 polymorphism associated with abnormal splicing is absent in African populations. *Immunogenetics* 2002; 53: 980-983.

Osmanov S, Patton C, Walker N, Schwardlander B, Esparza J and the WHO-UNIADS Network for HIV Isolation and Characterization. *Journal of AIDS* 2002; 29:184-190.

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Opi S, Peloponese J-M Jr, Esquieu D, Campbell G, de Mareuil J, Walburger A, Solomiac M, Gregoire C, Bouveret E, Yirrell DL and Loret EP. Tat HIV-1 primary and tertiary structures critical to immune response against non-homologous variants. *Journal of Biological Chemistry* 2002; **277**: 35915-35919.

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Title	NATURAL HISTORY COHORT (NHC) STUDY MRC Programme on AIDS in Uganda
Country	Uganda
LSHTM staff	Lieve Van der Paal, Jimmy Whitworth
Collaborators	
Funding	MRC
Dates	1990 – present

Summary

In 1990, a random selection of one third of the HIV-1 seropositive adults identified from the initial survey round of the general population cohort were invited to enrol into a natural history cohort (NHC) as prevalent cases. Seroconvertors identified during subsequent rounds are enrolled as incident cases. Seronegative controls for the prevalent and incident cases are randomly selected from the general population cohort and invited to enrol in the NHC. There is no replacement selection if the case or the control failed to enrol. In addition, in 1993 negative spouses of all the identified HIV-positives in the general population cohort were also requested to enrol (negative discordants). In 1999, we also added a “special” category, which includes individuals who are probably HIV-negative, but have repeatedly positive ELISA results and/or indeterminate Western Blots (who have previously been included in the negative category). The HIV-negative discordant and negative control groups have been combined since few individuals remain in a discordant relationship. Following informed consent, participants are invited to attend a study clinic every three months. During these regular appointments they are seen by clinicians who administer a detailed medical and sexual history questionnaire and undertake a full physical examination. Participants are also requested to attend the clinic for the investigation and treatment of medical problems occurring between routine appointments.

The NHC aims to:

- Determine the rate of HIV-disease progression, including survival times to AIDS and death;
- Describe disease manifestations;
- Identify risk factors for progression;
- Relate virological and other markers to disease stage and progression.

Publications

Morgan D, Mahe C, Mayanja B, Okongo JM, Lubega R and **Whitworth JAG**. HIV-1 infection in rural Africa: is there a difference in median time to AIDS and survival compared with that in industrialized countries? *AIDS* 2002; **16**: 597-603.

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Morgan D, Mahe C, Mayanja B and **Whitworth JAG**. Progression to symptomatic disease in people infected with HIV-1 in rural Uganda: prospective cohort study. *British Medical Journal* 2002; **324**: 193-197.

2.5 Tuberculosis

Title	EPIDEMIOLOGY OF MYCOBACTERIAL AND HIV INFECTIONS IN NORTHERN MALAWI
Country	Malawi
LSHTM staff	Paul Fine, Mia Crampin, Judith Glynn, Sian Floyd, Keith Branson
Collaborators	<ul style="list-style-type: none"> • Dr Bagrey Ngwira, Frank Mwaungulu (Karonga Prevention Study Malawi) • Dr Francis Drobniowski (PHLS Mycobacterium Reference Laboratory, Dulwich, UK) • Dr Sebastian Lucas (UMDS, St Thomas's Hospital, London, UK)
Funding	<ul style="list-style-type: none"> • Wellcome Trust • LEPR

Summary

Objectives

Studies of the relationship between HIV and mycobacterial disease.

Methods

The Karonga Prevention Study in Northern Malawi includes a case-control study of risk factors for tuberculosis and leprosy, including HIV. This started in 1988. Interim analyses showed the expected strong association with tuberculosis, but no association with leprosy. Further analyses will examine whether the association changes over time, with the proportion of HIV-infected individuals who are immunocompromised. A new phase of the case-control study is examining additional risk factors for TB. A retrospective cohort study also examined the association between HIV and TB in this population.

Publications

Mwaungulu F, Crampin AC, Kanyongoloka H, Mwafulirwa DT, Mwaungulu NJ, Glynn JR, Yates M, Drobniowski F, Fine PEM. Antituberculosis drug resistance in Karonga District: pattern and trend, 1986-2001. *Malawi Medical Journal* 2002;13:3-6.

Crampin AC, Floyd S, Mwaungulu F, Black G, Ndhlovu R, Mwaiyeghele E, Glynn JR, Warndorff DK, Fine PEM. Comparison of two versus three smears in identifying culture-positive tuberculosis patients in a rural African setting with high HIV prevalence. *International Journal of Tuberculosis and Lung Disease* 2001;5:994-9

Crampin AC, Mwinuka, V, Malema SS, Glynn JR, Fine PEM. Field based random sampling without a sampling frame: control selection for a case control study in rural Africa. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 2001;95:481-3

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Glynn JR, Warndorff DK, Fine PEM, Msiska GK, Munthali MM, Pönnighaus JM. The impact of HIV on morbidity and mortality from tuberculosis in sub-Saharan Africa: a study in rural Malawi and review of the literature. *Health Transition Review* 1997;7(suppl 2):75-87.

Title **TUBERCULOSIS AND HIV DISEASE IN MINEWORKERS IN SOUTH AFRICA**

Country South Africa

LSHTM staff Alison Grant, Katherine Fielding, John Day, Richard Hayes, Liz Corbett, Lilani Kumaranayake, Debbie Muirhead

Collaborators

- Aurum Health Research, Welkom, South Africa
- Dick Chaisson (Johns Hopkins University, Baltimore, USA)
- Kevin De Cock (CDC Kenya)
- Keith Klugman (SAIMR, Johannesburg, South Africa)

Funding Aurum Health Research

Dates October 1998 – December 2003

Summary

This is a collaborative project to carry out a series of studies of tuberculosis and HIV disease in South African mineworkers. Studies specifically concerning HIV which are in progress include:

1. *Effect of preventive therapy on disease episodes among HIV-infected mineworkers.*
HIV-infected employees have been recruited to a specialised clinical service delivering appropriate preventive therapies, in particular TB preventive therapy and cotrimoxazole. Using an incremental recruitment design, the efficacy of the preventive therapy in this population is being assessed in terms of its effect on hospital admissions (all-cause and cause-specific) and loss of working time. Data collection is complete, and analysis and write-up are in progress. We also plan to assess the cost-effectiveness of the service.
2. *Screening for TB prior to starting TB preventive therapy.*
We are using clinic data to evaluate a range of strategies to screening HIV-infected individuals for TB prior to starting TB preventive therapy. Data collection is complete, and write up is in progress.
3. *Evaluation of an employment-based antiretroviral programme.*
We are evaluating a workplace-based antiretroviral (ART) delivery programme with respect to feasibility, process, clinical and economic outcomes. In substudies, we are evaluating the counselling provided to individuals about to start ART, and investigating traditional medicine use in this population.
4. *Evaluation of the impact of a targeted core group intervention for women at high risk on STI prevalence, and HIV incidence among gold miners.*
A programme of education and improved STI treatment for women at high risk of STI/HIV in mining communities was implemented in 2000-2002. Data from the delayed intervention site are being used to measure HIV incidence in this community.
5. *A cohort study to investigate the effect of tuberculosis on the progression of HIV disease.*
HIV-infected miners are followed before, during and after an episode of tuberculosis to determine the effect of tuberculosis on HIV disease progression, as measured by HIV viral load. This study is complete and papers are in preparation. In an extension to this study, the effect of an episode of TB on the range of HIV quasispecies will be investigated.
6. *Pharyngeal carriage and antimicrobial resistance in isolates of Streptococcus pneumoniae in HIV-infected miners.*
A cross sectional study is in progress to examine the prevalence of nasopharyngeal carriage of pneumococci in HIV-infected and -uninfected individuals, the distribution of carriage serotypes in these groups and the effect of low-dose cotrimoxazole prophylaxis on the prevalence of carriage and of antimicrobial resistance.

Publications

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Title **THE PREVENTION OF MOTHER TO CHILD HIV TRANSMISSION AND PROTEST:
A COMBINED APPROACH**

Country Zambia

LSHTM staff Helen Ayles, Peter Godfrey-Faussett, Ginny Bond

Collaborators

- Margaret Siwale (MTCT Working Group, Lusaka, Zambia)
- Ignatius Kayewe (Kara Counselling and Training Trust, Lusaka, Zambia)
- Zambian HIV/AIDS Secretariat, NZP+, Zambia VCT Programme

Funding WHO

Dates

Summary

In countries with a high prevalence of HIV infection, the best available control strategies, promoted by the world's aid agencies and WHO, are failing to prevent the rising incidence of tuberculosis. Tuberculosis affects predominantly young, economically active, adults, on whom the development of the poorest countries depends. Recent initiatives aimed at preventing mother to child transmission of HIV are detecting women who are HIV positive, but are not addressing their healthcare needs in terms of prevention of opportunistic infections, TB detection, STI management etc.

A complete package of measures is needed to encompass both of these initiatives and to harness the community capacity that has arisen in most cities with a high prevalence of HIV. Such a package would reduce transmission of *M.tuberculosis* by improving case-finding and treatment; reduce reactivation of *M.tuberculosis* by establishing preventive therapy services and reduce transmission of HIV by enhancing voluntary HIV counselling and testing (VCT) services and reduce mother to child transmission.

The proposed innovation will:

- Encourage VCT and MTCT counselling and testing services as an entry point to integrated management and prevention of HIV-related TB, and STIs;
- Enhance collaboration between government health services and community organisations;
- Introduce TB-related issues into HIV-related social mobilisation and activism.

Its success will be measured by the impact on the community's burden of TB and other HIV related illness. Economic and social science evaluations will determine the potential cost-effectiveness and sustainability of the package. Success will also be measured by process indicators of demand for and acceptability of the package, equity of access to the services provided and cohort analysis of those treated for tuberculosis or with preventive therapy.

The ProTEST project is now in a country-wide expansion phase which is being funded by WHO and GFATM at country level. First phase expansion is already underway with this project starting in 3 new districts and the protocol incorporating ProTEST has been approved for the proposed roll-out of PMTCT in Zambia.

Title	COTRIMOXAZOLE PROPHYLAXIS IN HIV POSITIVE TUBERCULOSIS PATIENTS
Country	Malawi
LSHTM staff	Paul Fine, Mia Crampin, Sian Floyd, Judith Glynn
Collaborators	Dr Frank Mwaungulu (Karonga Prevention Study Malawi)
Funding	Wellcome Trust

Summary*Objectives*

To estimate the impact of cotrimoxazole prophylaxis on the survival of HIV-positive TB patients.

Methods

As part of the Karonga Prevention Study in Northern Malawi, End-of-treatment outcomes, and 18-month survival, were compared between TB patients registered in 1999 and 2000 in Karonga District, Malawi. Case ascertainment, treatment and outpatient follow-up were identical in the two years except that in 2000 cotrimoxazole prophylaxis was offered to HIV-positive patients in addition to routine care.

Results

The overall case fatality rate fell from 37% to 29%. Case fatality rates were unchanged in HIV negative patients in the two years but fell in HIV positive patients from 43% to 24%. The improved survival became apparent after the first two months and was maintained beyond the end of treatment. It was most marked in patients with smear positive TB and others with confirmed TB diagnoses.

Publications

Mwaungulu FBD, Floyd S, Crampin AC, Kasimba S, Malema S, Kanyongoloka H, Harries AD, Glynn JR, Fine PEM. Cotrimoxazole prophylaxis reduces mortality in HIV positive tuberculosis patients in Karonga District, Malawi (submitted).

Title	THE EFFECT OF HIV ON TB IN SOUTH AFRICAN GOLD MINERS
Country	South Africa
LSHTM staff	Pam Sonnenberg, Judith Glynn, Katherine Fielding, Peter Godfrey-Faussett
Collaborators	<ul style="list-style-type: none">• National Institute for Occupational Health• Jill Murray (University of Witwatersrand, Johannesburg, South Africa)• Stuart Shearer (Gold Fields Ltd)
Funding	Colt Foundation
Dates	1998 – 2003

Summary*Objectives*

Assess impact of HIV infection on incidence of tuberculosis.

Methodology

Retrospective cohort study of miners with known dates of seroconversion to HIV.

Results

Tuberculosis incidence was 2.90/100 pyar in HIV positive and 0.80/100 pyar in HIV negative miners: RR (adjusted for age and calendar period) 2.9, 95% CI 2.5-3.4. Restricting to those with known seroconversion dates showed a doubling in the incidence of TB within the first year of HIV infection (adjusted RR 2.1; 1.4-3.1), with only slight further increase in those infected for longer periods, up to 7 years. TB incidence was higher in HIV positive, than in HIV negative miners from 1992 onwards, and the proportion of TB attributable to HIV rose from 0% in 1991 to over 40%. There was a direct increase in those who were HIV-infected but also a doubling in TB incidence in those remaining HIV negative, implying considerable ongoing M tuberculosis transmission.

Publications

Sonnenberg P, Glynn JR, Fielding K, Murray J, **Godfrey-Faussett P,** Shearer S. HIV and pulmonary tuberculosis: the impact goes beyond those infected with HIV. AIDS 2003 (In Press).

Chapter 3. Factors that affect utilisation of care and prevention services for HIV/AIDS and STIs

3.1 Factors affecting HIV prevention and care

Title	THE SOCIAL IMPACT OF HIV/AIDS ON FAMILIES AND CHILDREN
Country	
LSHTM staff	Ian Timæus, Vicky Hosegood
Collaborators	<ul style="list-style-type: none"> • Kobus Herbst (Wellcome Africa Centre for Population and Reproductive Health, KwaZulu Natal, South Africa) • Julian May, Francie Lund (School of Development Studies, University of Natal, Durban, South Africa) • Anne Case (Princeton University, Princeton, USA)
Funding	<ul style="list-style-type: none"> • Wellcome Trust • Andrew W Mellon Foundation • NIH • DFID

Summary

The first main project in this area involves collaboration with the Wellcome Africa Centre for Population and Reproductive Health, Timæus and Hosegood have been analysing data from the Africa Centre's demographic surveillance system in northern KwaZulu-Natal to examine the impact of the death of a household member on household structure and the residential arrangements and well-being of children. One key finding is that child-headed households do not appear to have emerged in this rural area. Nevertheless, it is apparent that adult deaths often trigger the dissolution of households and children are also often fostered out at this time. Thus, being orphaned and the death of other of other adult relatives result in considerable social and physical mobility and disruption for children. Future research will also look at the impact of young adult deaths on the welfare of old people.

The quantitative research is complemented by a detailed ethnographic study of 10 households that have one or more adult members with AIDS. Fieldwork for this research is only now being completed. Nevertheless it is already yielding valuable results, such as the quality of care provided for AIDS patients in local clinics and hospitals and the difficulties that poor rural women encounter accessing the South African government's Child Support Grant.

Timæus is also collaborating with the School of Development Studies, University of Natal and other universities and research organisations to field a third round of the KwaZulu Natal Income Dynamics Study. The previous rounds of this household panel study were conducted in 1993 and 1998. The 2004 round is being commissioned by the South African Government's Department for Social Development with funding from DFID. This round of the study will have a strong focus on the impact of the HIV epidemic on the poverty and well-being of households and, in particular, the impact of the epidemic on children. The School is taking lead responsibility for the HIV-related aspects of the questionnaire and will lead the analysis in several fields, including the impact of adult ill-health and deaths on the educational outcomes experienced by children.

Publications

Hosegood, V. and Timæus, I. M. 'Household composition and dynamics in KwaZulu Natal, South Africa: Mirroring social reality in longitudinal data collection', in van de Walle, E. and Preston-Whyte, E. (eds). *African Households: an Exploration of Census Data*, Indiana University Press, in press.

Case, A., Hosegood, V and Lund, F. 'The reach of the South African Child Support Grant: Evidence from KwaZulu-Natal'. Centre for Social and Development Studies Working Paper 38, University of Natal, Durban, 2003.

Zungu, S., Moitse, S and Hosegood, V. 'Beating a path through a maze of bureaucracy. Social grants in rural areas.' *Children FIRST*. 7(47):5-8.

Hosegood, V., Herbst, K. and Timæus, I. M. 'The impact of adult AIDS deaths on households and children's living arrangements in rural South Africa'. Paper presented at the scientific meeting on Empirical Evidence for the Demographic and Socio-economic Impact of AIDS, Durban, South Africa. 26-28th March, 2003.

Hosegood, V., and Ford, K. 'The impact of HIV/AIDS on children's living arrangements and migration in rural South Africa'. Paper presented at the scientific meeting on African Migration and Urbanization in Comparative Perspective, Johannesburg, South Africa. 4-7th June, 2003.

Grassly, N. C., and Timæus, I. M. 'Orphans and AIDS in Sub-Saharan Africa'. Paper presented at the UN Population Division Workshop on HIV/AIDS and Adult Mortality in Developing Countries, New York, 8-13th September, 2003.

<http://www.un.org/esa/population/publications/adultmort/Adultmortality.htm>

Title	FOCUS ON MEN: A PROGRAMME TO INCREASE INVOLVEMENT IN SEXUAL AND REPRODUCTIVE HEALTH AMONG MALE SINGLE SEX HOSTEL DWELLERS IN JOHANNESBURG
Country	South Africa
LSHTM staff	Monique Oliff, Philippe Mayaud, Peter Vickerman, Charlotte Watts
Collaborators	Monique Oliff, Sinead Delany, Helen Rees (Reproductive Health Research Unit [RHRU], Johannesburg, South Africa)
Funding	European Commission
Dates	2002 – 2005

Summary*Rationale*

HIV prevalence continues to rise in South Africa. Although men are influential in decision-making around key aspects of sexual and reproductive health, particularly condom use, they seldom access public sector sexual and reproductive health services. The hostels in inner city Johannesburg are characterised by high rates of gender-based violence and STIs, and low rates of condom use. The men that live in these hostels are migrants with strong links to their traditional rural homesteads and the traditional values that govern sexual behaviour. The City of Johannesburg requested the support of the Reproductive Health Research Unit, to develop and intervention to increase condom use and utilisation of health care services, and to reduce STI prevalence in this population.

Study design

Ethnographic research was conducted in the hostels in order to inform the feasibility of an intervention in this environment. Additional physical and social mapping of the environment outside the hostels has been completed. A survey of sexual behaviour, STIs and HIV of 2000 hostel dwellers and women living in informal settlements, as well as an assessment of quality of care of health care services in the area is planned prior to the introduction of an intervention. The intervention is aimed at improving access to sexual and reproductive health services through innovative peer education programmes involving existing cultural and music groups, condom promotion and improved STI services in both the public and private sector. The survey of communities and facilities will be repeated in 2005.

The intervention is expected to increase health-seeking behaviour amongst men, as well as condom use. In addition, the study will measure the impact on STI prevalence. Mathematical modelling will be used to estimate cost-effectiveness of this intervention in reducing HIV infection in the population.

The study started in 2003 and will be completed by 2005.

Title	A VOUCHER SCHEME FOR ADOLESCENTS IN NICARAGUA TO IMPROVE THE UPTAKE OF REPRODUCTIVE HEALTH SERVICES
Country	Nicaragua
LSHTM staff	Anna C Gorter, Betty Kirkwood
Collaborators	Zoyla Segura MD, Liesbeth Meuwissen MD, Patricia Gonzalez MD (ICAS Instituto Centroamericano de la Salud - Central American Health Institute -)
Funding	DFID
Dates	June 2000 – May 2002

Summary

Adolescents in Nicaragua have limited access to sexual health care of low quality. A voucher scheme can provide a way to overcome these problems by providing an alternative to the existing model of health service provision. Instead of a centralised system deciding which health services will be provided, a voucher scheme can introduce quality control and competition, and give the power of choice to the consumer. Over time, a voucher scheme will engender changes in the provision of services based on the requirements of the users. Competition will encourage service providers to use innovative approaches to attract voucher holders.

In June 2000 a voucher project started to improve the uptake and quality of sexual health care for poor adolescents of Managua. It builds on work already carried out with female sex workers and their clients and which has demonstrated the particular ability of a voucher scheme to reach vulnerable groups, to achieve improved quality of health services and to reduce the prevalence and incidence of STIs in this group.

The project distributes vouchers entitling poor adolescents to a free consultation for sexual health care directly on streets, markets and recreational centres and through NGOs. Vouchers are redeemable at any one of 20 clinics (contracted in advance by competitive tender) for free educational materials, counselling, contraception, prenatal control and STI treatment. Human and technical performance is monitored and clinics not meeting the quality targets are removed from the scheme.

Title	AMREF MINE HEALTH PROJECT
Country	Tanzania
LSHTM staff	Deborah Watson-Jones, David Ross
Collaborators	<ul style="list-style-type: none"> • Meghan DiCarlo, Awene Gavyole (African Medical & Research Foundation) Kahama Mining Corporation • Geita Goldmine • National Institute of Medical Research, Mwanza, Tanzania
Funding	<ul style="list-style-type: none"> • Kahama Mining Corporation • Geita Goldmine • DTP • Stanley Mining
Dates	2000 – 2003

Summary

Objectives

To develop and manage a sustainable of community-based health programmes minimize the impact of HIV, STIs, lung diseases and malaria among mineworkers, female bar workers and communities surrounding mining areas of the Lake Zone of Tanzania.

Methodology

Key activities:

1. Mine site
Mineworker peer health educator (PHEs) scheme and HIV/STI/TB/Malaria Awareness programmes;
2. Community
Community health educators (CHEs) scheme, social marketing of condoms and insecticide treated bed nets, Annual Health Week, production of locally appropriate health promotion materials, focused interventions for high-risk groups e.g. female bar workers;
3. Health facilities
Health worker training and supervision of selected health units in partnership with District Health Authorities, establishment of community HIV Information Centres with VCT (joint venture with District health department also offering other SRH services and ongoing post-test counselling and support).

Results

Baseline cross-sectional surveys in 2 mining communities conducted in 2000 and 2001 demonstrated a 16% HIV prevalence in men and 18% in women, compared to 4-10% in male mine workers and 42% in female bar workers. Over 50% of men reported paying for sex during the previous year.

Project prevention activities started in 2001 including PHE schemes, condom promotion and bednet social marketing, focused interventions targeting bar workers and their male clients. HIV Information Centres offering VCT, syndromic STD management and FP have been established in 2002.

An interim survey in one of the mine communities was conducted in April 2003. There has been no significant change in HIV prevalence since 2000 in the groups surveyed, with the exception of female bar and facility workers where the proportion who had HIV infection was significantly lower in 2003 (30%) compared to 2000 (45%). 21% of female mineworkers, surveyed for the first time in 2003, had HIV infection.

PHE are currently being trained in a 3rd mine, North Mara Mine (owned by PlacerDome).

The project is also providing technical assistance in the development of Geita GoldMine's company HIV policy.

Publications

Clift S, Anenoma A, **Watson-Jones D**, Kanga Z, Ndeki L, Changalucha J, Gavyole A, **Ross D**. Variations of HIV and STI prevalences within communities neighbouring new goldmines in Tanzania: importance for intervention design. *Sexually Transmitted Infections* 2003;79:307-12.

In preparation

Desmond, N., Allen, C., Clift, S., Plummer, M., Bugeke, G., Justine, B., Medard, L., Mzugu, J., **Watson-Jones, D.**, Wight, D., **Ross, D.** A typology of groups at risk of HIV/AIDS/ STI in a mining location in northern Tanzania revealed using qualitative methods. Submitted to *Social Science and Medicine*.

3.2 Factors affecting STI care

Title	THE RELATIONSHIP BETWEEN GYNAECOLOGICAL MORBIDITY, REPRODUCTIVE TRACT INFECTIONS AND COMMON MENTAL DISORDERS IN GOA
Country	India
LSHTM staff	Vikram Patel, David Mabey, Betty Kirkwood, Tamara Hurst, Helen Weiss
Funding	Wellcome Trust
Dates	October 2000 – October 2005

Summary

Reproductive tract symptoms, in particular the complaint of abnormal vaginal discharge, are amongst the most common health complaints in women in South Asia. The complaint of vaginal discharge is assumed to be the result of one of five Reproductive Tract Infections (RTIs) which, in part, explains its public health significance. Thus, RTIs are potential markers for unsafe sexual behaviour, and are associated with adverse health outcomes such as infertility, increased vulnerability for HIV/AIDS and premature labour. Two recent studies from Bangladesh and New Delhi located in gynaecological or maternal health settings and employed standardised diagnostic tests reported an overall prevalence of RTIs of 30% and 60% respectively in women with the complaint of abnormal vaginal discharge. Thus, at least 50% of the complaints are 'medically unexplained'. The aim of this study is to investigate the aetiology of the complaint of vaginal discharge (and other common gynaecological complaints), in particular to test the hypothesis that psychosocial factors such as somatization, depression and social difficulties are an important cause. The study is a community cohort study of women aged 18-50 living in the Aldona primary health centre catchment population in the state of Goa in west India. The study has completed its recruitment phase (2494 women recruited, representing 82% of the sample randomly selected from a community population). The final 12 month reviews will be completed by May 2004. Analyses of the recruitment data show that the prevalence of the complaint is 14.5%, the prevalence of any RTI is 26.7% (any STI is 4%) and the prevalence of clinically significant depression or anxiety is 6.7%. While 30% of women with vaginal discharge have an RTI, there is a strong association between depressive and anxiety disorders (17% vs 5%) and somatoform complaints with the symptom of vaginal discharge. Stressors such as financial difficulties, restrictions on women's decision making and sexual violence are associated with these complaints. Women attribute their complaints to stress in their personal lives (35%). Multivariate analyses show that depression, somatoform symptoms and RTIs are all significantly associated with the complaint of vaginal discharge. The syndrome of vaginal discharge is associated with considerable disability and health care costs. The analyses of the cohort data will help tease out causal relationships. The implications of this study will be to help develop new interventions for common gynecological complaints which target both the infectious and non-infectious aetiologies including mental health and social problems.

Publications

Tanksale VS, Sahasrabhojane M, Gomes B, Viegas R, Nevrekar P, Menezes S, **Patel V, Mabey D**. The reliability of a structured examination protocol and self-administered vaginal swabs: a pilot study in Goa, India. *Sex. Transm. Inf.* 2003.

Title	IMPROVING THE QUALITY OF STI CARE IN THE PRIVATE SECTOR, SOUTH AFRICA: A DISTRICT BASED MULTIPRONGED APPROACH
Country	South Africa
LSHTM staff	Ruairi Brugha, Anthony Zwi
Collaborators	Helen Schneider, Nzapfurundi Chakibuli (Centre for Health Policy, University of Witwatersrand, Johannesburg, South Africa)
Funding	Wellcome Trust
Dates	March 2000 – December 2002

Summary

The purpose of the study is to develop and test interventions that promote evidence-based management of sexually transmitted infections (STI) by GPs at the district level in urban South Africa. The main assumption underlying the study approach and combination of interventions is that several factors and actors at the local and national level contribute to the success or failure of clinical guideline implementation.

Objectives

to design, implement and evaluate strategies to improve the quality of STI care in the private sector through the effective implementation of syndromic management.

Methodology

The study has used a quasi-experimental design, with baseline and follow-up assessment of quality and equity of privately provided STI care in two intervention and one control district. The interventions are targeted at health workers and public sector managers in the first district; and additionally with community representatives in the second site. Follow-up in all 3 districts includes GP record reviews.

Results

Analysis of results ongoing.

Publications

Chabikuli N, Schneider H, Blaauw D, Zwi A, Brugha R. Quality and equity of privately provided sexually transmitted diseases care in South Africa. *Health Policy and Planning* 2002; 17(Suppl 1): 40-46

International AIDS Conference, Barcelona, July 2002.

International AIDS Conference, Durban, July 2000.

Title	EVALUATION OF PERFORMANCE, COSTS AND ACCEPTABILITY OF DIFFERENT MANAGEMENT APPROACHES TO VAGINAL DISCHARGE IN SOFIA, BULGARIA
Country	Bulgaria
LSHTM staff	Philippe Mayaud, Fern Terris-Prestholt
Collaborators	<ul style="list-style-type: none"> Nadine Cornier, Arnaud Janin (Médecins Sans Frontières [MSF], Switzerland and Bulgaria) Philippe Cavailler (Epicentre, France & MSF Switzerland)
Funding	<ul style="list-style-type: none"> Swiss Cooperation Médecins Sans Frontières
Dates	2001 – 2004

Summary

Background

Bulgaria has been experiencing tremendous sociological and structural changes rapidly which have affected the health sector. STI are soaring and STI management relies on outdated vertical and stigmatising public health services, whilst the simplified WHO-promoted syndromic approach is still resisted by many health professionals. MSF has been supporting the establishment of a model STI clinic in Sofia, which aims to offer confidential and quality reproductive and sexual health services to marginalised populations (gypsies, male and female sex workers, drug users), and Bulgarian youth.

Aims

Research will be conducted by the MSF team to evaluate the burden of STI and the operational and economic performance of syndromic management and current STI management practices in the Bulgarian context, through a series of studies:

- Providing baseline information on the prevalence and risk factors of different STI at the MSF clinic;
- Evaluating the validity of various algorithms for the management of vaginal discharge and detection of cervical infections among symptomatic women presenting to the clinic;
- Evaluating the costs of the various approaches from the various providers perspective (MSF and Bulgarian public health system);
- Evaluating the acceptability of syndromic management from the patients and providers' perspectives.

Preliminary results for study 1

Between September 2001 and July 2002, 424 women with confirmed vaginal discharge were enrolled in these studies. The prevalence of cervical infections (*N gonorrhoeae* and/or *C trachomatis*) was 9.5% and those of vaginal infections were: 2.5% for trichomoniasis, 35.5% for bacterial vaginosis, and 23% for candidiasis. In addition, 2.5% of women had active syphilis and 38% of women were found to harbour human papilloma virus (HPV) strains, most of which were of oncogenic types. 32 (27%) of 118 women with HPV had evidence of cervical dysplasia. This is the first study of HPV and dysplasia in Bulgaria. Preliminary evaluation of currently used algorithms show good performance of the syndromic approach.

Conferences

Cavailler P, Cornier N, Berzow P, et al. Estimation of STD prevalence and algorithm validation among women presenting with vaginal discharge at the MSF STD clinic in Sofia, Bulgaria. MSF Annual Scientific Conference, Paris, May 2002.

Chapter 4. Impact and cost-effectiveness of interventions

4.1 Adolescents

Title	ADOLESCENT REPRODUCTIVE HEALTH INTERVENTION TRIAL, MWANZA: STRATEGIES FOR THE PREVENTION OF HIV INFECTION AND THE ENHANCEMENT OF REPRODUCTIVE HEALTH AMONG ADOLESCENTS IN RURAL TANZANIA (MEMA KWA VIJANA PROJECT)
Country	Tanzania
LSHTM staff	Alessandra Anemona, Dean Everett, Heiner Grosskurth, Richard Hayes, Lilani Kumaranayake, David Mabey, Angela Obasi, Mary Plummer, David Ross (Director), Fern Terris-Prestholt, James Todd
Collaborators	<ul style="list-style-type: none">• African Medical and Research Foundation (AMREF), Tanzania• MRC, SPHSU, Glasgow, UK• Ministry of Education and Culture, Tanzania• Ministry of Health, Tanzania• National Institute for Medical Research (NIMR), Tanzania• University of Manitoba, Canada
Funding	<ul style="list-style-type: none">• European Commission• Ireland Aid• Medical Research Council, UK• Department for International Development (DFID), UK• UNAIDS
Dates	October 1997 – December 2002

Summary

This project aims to develop and rigorously evaluate an intervention aimed at improving the reproductive health of adolescents in four rural districts of Mwanza Region, Tanzania.

The objective of the intervention is to reduce sexual risk behaviour and the prevalence and incidence of HIV and other STIs in adolescents, and to increase their use of effective contraceptive methods. An intervention package has been designed based on the curriculum of the Tanzanian Ministry of Education and is being implemented among adolescents attending the last three years of primary school in ten rural communities that include 62 primary schools and 18 health facilities. The intervention uses innovative learning methods, and includes teacher-led classroom sessions on reproductive health and risk reduction, peer education directed at adolescents who are both in and out of school, the provision of youth-friendly reproductive health and family planning services (both in health facilities and through youth condom promoters and distributors), and outreach activities in the community.

The impact is being evaluated through a community-randomised trial in which ten intervention and ten comparison communities are compared. In 1997-98, an initial survey was conducted among 9,436 adolescents aged 15-19 years to ensure comparability of the two groups through appropriate stratification of the study communities prior to randomisation. This survey showed that the prevalence of HIV rose from 0.2% in 15 year-old males to 1.0% in 19 year-old males. In females, the HIV prevalence rose from 0.9% to 4.6% over the same age range. The prevalence of *Chlamydia trachomatis* (CT) also increased with age and was lower in males than in females. In males, the prevalence of CT rose from 0.4% at 15 years to 1.7% at 19 years, and in females it increased from 1.8% at 15 years to 3.2% at 19 years.

In each community, a cohort of between 402 and 563 primary school pupils aged 14 and above was recruited in late 1998 (total 9,291 participants), and is being followed-up for three years. This cohort is being used to measure the impact of the intervention on the sero-incidence of HIV, syphilis and *Herpes simplex virus-2* infection, the prevalence of gonorrhoea and chlamydia and the incidence of pregnancy. Knowledge and attitudes related to sexual and reproductive health, sexual risk behaviour and use of contraceptive methods are being evaluated through a variety of methods (in collaboration with the MRC-funded Health & Lifestyles Research Programme in Mwanza). Feasibility and cost-effectiveness are being assessed, and a detailed process evaluation is an integral part of the project. The final follow-up survey of the trial cohort started in late September 2001, and the main trial results are expected by December 2002.

Publications for 2001/02 (for conference abstracts, see Annex; for earlier Mwanza work see previous Annual reports):

Obasi A, Balira R, **Todd J**, **Ross DA**, Changalucha J, Mosha F, **Grosskurth H**, Peeling R, **Mabey DCW**, **Hayes RJ**. Prevalence of HIV and *Chlamydia trachomatis* infection in 15 to 19 year olds in rural Tanzania. *Trop Med Internat Hlth* 2001;**6**:517-525.

Goodburn EA, **Ross DA**. Young people's health in developing countries: a neglected problem and opportunity. *Health Policy & Planning* 2000;**15**:137-144.

Ross DA. Good things for young people. *LSHTM Alumni News* 2001;**21**:3.

Fox R. Tanzanian AIDS project works towards "good things for young people". *Lancet* 2000;**355**:1703.

Title	A PILOT STUDY TO ASSESS THE ACCEPTABILITY AND FEASIBILITY OF CONDUCTING A COMMUNITY RANDOMISED TRIAL OF AN ADOLESCENT REPRODUCTIVE HEALTH INTERVENTION IN ZIMBABWE
Country	Zimbabwe
LSHTM staff	Richard Hayes, Shabbar Jaffar, David Mabey
Collaborators	<ul style="list-style-type: none">• Mary Bassett, David Wilson (University of Zimbabwe)• Frances Cowan, Judith Stephenson, Anne Johnson (UCL)• David Brown (PHLS)
Funding	Wellcome Trust
Dates	October 1999 – March 2001

Summary

Zimbabwe has seen an abrupt and violent HIV epidemic with prevalence of HIV among adults in some cities near 30%. The final aim of this research is to conduct a community-randomised trial to determine the effectiveness of a targeted adolescent sexual health intervention. The intervention will comprise an enhanced school-based sex education programme combined with provision of youth-friendly sexual health services. It is proposed to randomise 30 secondary schools to the intervention and comparison arms. A cohort of pupils aged 12 and over will be recruited and followed up for 4 years to measure the impact of the intervention on the incidence of HIV, STIs and unintended pregnancy.

An initial *pilot study* has been funded by the Wellcome Trust to assess the feasibility and acceptability of conducting the main trial, to develop and pre-test the intervention and data collection methods, and to collect data on HIV/STI prevalence rates and other variables that will help to refine the design of the main trial. In collaboration with PHLS, a urinary assay for HSV2 antibodies will be developed and validated.

Title	REGAI DZIVE SHIRI: A RANDOMISED TRIAL OF HIV/STD PREVENTION AMONG ZIMBABWEAN YOUTH
Country	Zimbabwe
LSHTM staff	Richard Hayes, Shabbar Jaffar
Collaborators	<ul style="list-style-type: none"> • University College • University of Zimbabwe
Funding	NIH
Dates	September 2002 – August 2007

Summary

Zimbabwe has one of the most severe HIV epidemics in the world. The development of effective interventions to protect the next generation of young people from infection is a major public health priority. School-based interventions offer a potentially efficient method of reaching the target population, but their effectiveness needs to be evaluated before wide-scale implementation can be recommended.

The aim of the project is to implement and rigorously evaluate an exciting and innovative adolescent HIV/STD prevention programme involving school students, professional peer educators, teachers, parents, rural health clinics and the wider community, by means of a community randomised trial.

Primary objective:

- To measure the effectiveness of an adolescent HIV prevention intervention, delivered to secondary school pupils and the wider community, in reducing the incidence of HIV infection, the incidence and prevalence of other STIs and the incidence of unintended pregnancy among the students.

Secondary objectives

- To use a combination of quantitative and qualitative research methods to explore the evolution of sexual behaviour in adolescents in rural Zimbabwe;
- To assess the impact of the intervention on knowledge and attitudes regarding reproductive and sexual health, reported behaviour, and measures of self-efficacy;
- To determine through rigorous process evaluation whether these programmes are delivered as intended;
- To refine and assess the validity of research instruments for measuring sexual behaviour among Zimbabwean adolescents;
- To examine through rigorous process evaluation the acceptability and feasibility of providing VCT in rural community settings;
- To study the epidemiology of Herpes simplex virus type-2 (HSV2) infection among adolescents, and to measure the extent to which HSV2 facilitates acquisition of HIV infection.

Methods

30 communities (60 secondary schools) will be randomly allocated to either early or deferred programme implementation. Communities in the deferred arm will have HIV prevention as currently implemented. The impact of the programme will be measured in a cohort of 6,600 Form 2 secondary school pupils aged >12 (median age 15), who will be followed for 4 years (to median age 19). Participants will be surveyed at the start of the project, after 30 months and after 4 years. At each survey they will complete a questionnaire and provide a finger-prick blood sample (and a urine sample for girls). The impact of the programme on cumulative incidence of HIV and HSV2 infection, and unintended pregnancy as well as on reported sexual behaviour will be determined. A detailed process evaluation of the programme will be conducted to inform wider programme implementation.

4.2 High-risk groups

Title	VAGINAL MICROBICIDES FOR THE PREVENTION OF HIV TRANSMISSION: A FEASIBILITY STUDY FOR PHASE III TRIALS IN MWANZA REGION, TANZANIA
Country	Tanzania
LSHTM staff	Richard Hayes, David Ross, Andrew Vallely, Tobias Chirwa, Dean Everett
Collaborators	<ul style="list-style-type: none">• AMREF• NIMR• MRC Clinical Trials Unit• MRC Social and Public Health Science Unit
Funding	<ul style="list-style-type: none">• DFID• MRC
Dates	October 2001 – September 2003

Summary

Objectives

The aim of this feasibility study is to investigate whether high-risk women in Mwanza City would be a suitable group for Phase III (efficacy) trials of vaginal microbicides such as dextrin sulphate, PRO 2000 or others.

The specific objectives of the feasibility study will be:

- To determine whether it is possible to recruit and follow-up sufficient numbers of high-risk women in this site;
- To estimate HIV incidence among these women;
- To estimate condom use among these women.

Methodology

This feasibility study will be linked to an AMREF Women's Reproductive Health Project which will be established in Mwanza City. Between 10 and 15 weekly women's reproductive health clinics will be set up in different areas of the city. The clinics will be run by mobile teams, and each clinic will operate on a fixed day each week. Women working in food and recreational facilities (bars, hotels, restaurants, discos etc.), who are assumed to be at high risk of HIV and other STIs, will be invited to participate in the project. Consenting women will be recruited at their nearest project clinic, and then followed up at routine clinic visits every three months. They will also be encouraged to attend the clinic at other times if necessary. Periodic serum samples, genital swabs and urine will be collected to measure the prevalence and incidence of HIV and other STIs including syphilis, HSV2, gonorrhoea, chlamydia, trichomoniasis and bacterial vaginosis. Detailed data will also be collected on the demographic and behavioural characteristics of the women. Recruitment commenced in September 2002.

A linked social science project will be carried out using a mix of quantitative and qualitative research methods. The main objectives will be to characterise sexual behaviour (including condom use) among high risk women and their sexual partners; to determine the acceptability of vaginal gel and applicators among high risk women and their sexual partners; and to identify the obstacles and facilitating factors to continued involvement in the microbicide research programme by high risk women.

Title	EPIDEMIOLOGICAL MODELLING OF MICROBICIDES IMPACT AND COST-EFFECTIVENESS
Countries	Cameroon, Uganda, South Africa, Zambia
LSHTM staff	Charlotte Watts, Peter Vickerman, Anna Foss
Collaborators	<ul style="list-style-type: none"> • Clinical Trials Unit, MRC • Geoff Garnett, Imperial College, London, UK • Scientists collaborating in microbicide trials (RHRU)
Funding	<ul style="list-style-type: none"> • DFID • MRC
Dates	2001 – 2005

Summary

The Microbicides Development Programme will trial the impact of new microbicides for HIV prevention. In practise microbicide impact will be affected by many contextual factors, including patterns of sexual behaviour, condom use, and STD and HIV infection. Stochastic and deterministic mathematical models of HIV and STD transmission incorporating a microbicide will be used to:

- Explore issues in the design of trials of microbicides;
- Explore the population level impact and cost-effectiveness of vaginal-microbicides with different levels of efficacy, coverage and patterns of use;
- Investigate factors influencing the potential impact of a vaginal microbicide used in different settings;
- Identify optimal strategies for the use of a vaginal microbicide in combination with other methods of HIV prevention;
- Estimate the per sex-act efficacy of a vaginal microbicide, controlling for sexual behaviour, STD infection and condom use (using the Phase III trial behavioural, epidemiological and impact data);
- The models will include the role of other STDs in HIV transmission, the potential indirect protection provided by microbicides that are active against STDs, and the impact of concurrent forms of HIV prevention. The modelling will use behavioural data from the trial sites, and build upon work conducted by Watts and Vickerman (2000).

Publications

Plenary presentation Microbicides 2002: Watts (2002) The public health impact of microbicides
Foss A., Vickerman P., Heise L., Watts C (2003) *Shifts in condom use following microbicide introduction: Should we be concerned?* AIDS 17.

Presentations

Presentations to International Partnership on Microbicides November 2003, International Family Health Advisory Committee October 2003, Meeting of Advocates on microbicides November 2003.

Title	PERIODIC PRESUMPTIVE TREATMENT OF SEXUALLY TRANSMITTED INFECTIONS AMONG FEMALE SEX WORKERS: A MULTICENTER TRIAL
Countries	Benin, Ghana
LSHTM staff	Philippe Mayaud, David Mabey
Collaborators	<ul style="list-style-type: none"> Annie-Claude Labbé, Honoré Meda, Cyriaque Gnintoungbe (Benin site) Khonde Nzambi, Comfort Asamoah-Adu, Agnes Dzokoto (Ghana site) Michel Alary (Centre hospitalier affilié universitaire de Québec, Université Laval, Canada) Jacques Pépin (Centre for International Health, Université de Sherbrooke, Canada)
Funding	<ul style="list-style-type: none"> Canadian Agency for International Development (CIDA) Canadian Institutes of Health Research (CIHR) American Society for Tropical Medicine and Hygiene (ASTMH) DFID KP on HIV/AIDS & STIs
Dates	April 2001 – August 2002 (completed)

Summary

Rationale and Methodology

In West Africa, female sex workers (FSW) and their clients constitute important core groups in the transmission of STI. There are no easy method to detect and screen common STI such as *Neisseria gonorrhoeae* (NG) and *Chlamydia trachomatis* (CT) in these groups. Treatment relies on the syndromic approach, which requires that infected individuals at least display symptoms and signs, but these infections are often symptomless. An alternative approach, presumptive treatment (PPT), does not rely on diagnostic tests and offers the possibility of selecting core groups with high rates of both STIs and sexual partner change. This approach has been successfully used for syphilis control, but few studies on selective treatment of NG and CT have been conducted.

The study is a community-randomised double-blind placebo-controlled trial of PPT of NG/CT administered monthly for 10 months to FSWs in Benin and Ghana with the aims to determine the impact of this strategy on:

- NG/CT prevalence among the FSWs (main outcome);
- NG/CT prevalence among clients in the same areas;
- HIV incidence among FSW;
- Bacterial drug resistance (antibiotics to be used are: ciprofloxacin and azithromycin).

Treatment consisted of supervised intake of azithromycin (1g) at month 1, and ciprofloxacin (500mg) at months 2 and 3 (or corresponding placebos), with this 3-month cycle repeated twice more over 9 months

Main results/outcomes

Two randomisation strategies were used: community-cluster randomisation in Accra, Ghana (n=384) and in peripheral sites of Cotonou and Porto-Novo, Bénin (n=252); and standard 1:1 randomisation for the rest of the eligible population in Benin sites (n=181).

Overall, 71% of the “eligible” monthly doses were effectively received. Adherence was slightly higher in Ghana than in Bénin (73% vs. 70%), and higher for the months during which azithromycin was distributed (75.5% vs. 69% for ciprofloxacin months). Lack of compliance with study regimen was associated with mobility of women (88%), rather than refusal (11%), or pregnancy (1%). Adverse effects were reported more frequently for azithromycin (28% vs. 22% in placebo) and least for ciprofloxacin (11% in both treatment and placebo groups).

Follow-up cervical samples were obtained from 80% of participants. NG prevalence decreased from 13.5% to 7.3% in the intervention group, and from 16.2% to 11.6% in the placebo group; however the overall reduction in prevalence did not differ significantly between the groups. There was no effect of the intervention on CT prevalence among FSW. NG and CT prevalence in clients decreased in both groups (from 3.0% to 1.9% for NG and from 4.2% to 2.9% for CT). There was no increase in NG antimicrobial resistance.

In conclusion, PPT may not be a useful strategy when other control measures have already been successful.

Publications

Labbé AC, Dzokoto A, Nzambi K, Asamoah-Adu C, Pépin J, Meda H, **Mabey D, Mayaud P**, Alary M. Trial of periodic presumptive treatment of gonorrhoea and chlamydia infections among female sex workers in Benin and Ghana: adherence to treatment schedule over a 9-month period. Ghana. Abstract to the 15th Meeting of ISSTD, Ottawa, Canada. 27-30 July 2003

Labbé AC, Dzokoto A, Nzambi K, Asamoah-Adu C, Pépin J, Meda H, **Mabey D, Mayaud P**, Alary M. A randomised placebo-controlled trial of routine monthly antibiotics against gonococcal and chlamydial infections among female sex workers in Ghana and Bénin: intention-to-treat analysis. Abstract to the 15th Meeting of ISSTD, Ottawa, Canada. 27-30 July 2003.

Title	A PILOT STUDY TO ASSESS THE ACCEPTABILITY AND FEASIBILITY OF CONDUCTING A COMMUNITY RANDOMISED TRIAL OF A TARGETED HIV PREVENTION INTERVENTION AMONG SWS
Country	Zimbabwe
LSHTM staff	Richard Hayes, Shabbar Jaffar, David Mabey
Collaborators	<ul style="list-style-type: none"> • David Wilson, Mary Bassett (University of Zimbabwe) • Frances Cowan, Judith Stephenson, Anne Johnson, (UCL)
Funding	Wellcome Trust
Dates	October 1999 – March 2001

Summary

Zimbabwe has seen an abrupt and violent HIV epidemic with prevalence of HIV among adults in some cities near 30%. The final aim of this research is to conduct a community randomised trial to test the effectiveness and cost-effectiveness of targeting HIV prevention interventions through SWs. It is planned that about 20 communities will be randomised to either intervention or comparison arms of the study. The targeted intervention will consist of giving periodic presumptive treatment (PPT) of STIs to SWs via a community nurse, in addition to using peer educators to promote safer sex and maximise condom use among these women. By involving peer educators in intervention delivery we hope to make it sustainable and acceptable. The primary outcome measure would be difference in HIV incidence in male migrant workers between intervention and comparison communities after two years. Secondary outcome measures will include differences in rates of bacterial STIs in SWs and migrant workers and the population attributable fraction (PAF) for incident HIV infection associated with past or incident HSV-2 infection will be calculated.

The aims of this pilot study are: a) to determine the extent to which a mature HIV epidemic, such as the one in Zimbabwe, is driven by commercial sex, b) to develop an acceptable and sustainable HIV prevention intervention targeted through SWs, c) to determine the feasibility of undertaking a community randomised trial to test effectiveness and cost effectiveness of the targeted intervention in reducing HIV incidence in the wider population, and d) to develop and evaluate a urinary assay for HSV-2 antibody, to be used as a biomedical outcome measure in the proposed trial.

A cross-sectional survey was completed in 1405 men, working on commercial farms or in mines. Urine testing revealed an HIV prevalence of 27%, but a low prevalence of other STIs (chlamydia 1.5%, gonorrhoea 0.5%). 29% of men reported sex with a SW in the past year. HIV infection was more common in men reporting SW contact (OR 1.9, 95% CI 1.5-2.5).

Publications

Cowan FM, Lanhaug L, Hargrove J, Jaffar S, Mhuriyengwe L, Swarthout TD, Matsikire E, Peeling R, Latif A, Bassett M, Brown DWG, Mabey D, Hayes RJ, Wilson D. Is contact with sex workers important in driving the HIV epidemic in rural Zimbabwe? In preparation.

4.3 Communities

Title	THE IMPACT AND COST-EFFECTIVENESS OF HIV PREVENTION STRATEGIES IN SUB-SAHARAN AFRICA: A COMPARATIVE ANALYSIS OF FOUR STRATEGIES EVALUATED IN THREE RANDOMISED TRIALS (STDSIM PROJECT)
Countries	Africa – general
LSHTM staff	Richard White, Kate Orroth, James Todd, David Ross, Alessandra Anemona, David Mabey, Heiner Grosskurth, Richard Hayes; Lilani Kumaranayake, Fern Terris-Prestholt
Collaborators	<ul style="list-style-type: none"> • Eline Korenromp, Dik Habbema (Erasmus University Rotterdam) • David Serwadda, Nelson Sewankambo, Fred Wabwire, Tom Lutalo, • Ronald Gray, Maria Wawer (Rakai Research Programme of the Uganda Virus Research Institute and Johns Hopkins University) • Anatoli Kamali, Jessica Nakiyingi, Lawrence Muhangi, Jimmy Whitworth (MRC Programme on AIDS, Uganda Virus Research Institute) • Wambura Mwita (National Institute for Medical Research Tanzania)
Funding	DFID
Dates	December 1998 – July 2003

Summary

Background

Primary prevention of HIV infection remains a very high priority. Programmes to promote safer sexual behaviour and improved treatment services for STDs have been advocated as complementary strategies for HIV control. There is strong evidence to suggest STDs enhance the transmission of HIV, so better treatment services should result in lower STD prevalence and reduced incidence of HIV.

Three trials have been carried out in Tanzania and Uganda to evaluate the impact of these intervention strategies. A trial in Mwanza, Tanzania found that improved syndromic STD management implemented through government health units led to a 40% reduction in HIV incidence, and was highly cost-effective. A second trial in Rakai, Uganda found that periodic mass STD treatment of all adults had no significant impact on HIV incidence. A third trial in Masaka, Uganda found that a behaviour change programme, with or without improved syndromic STD management, had no significant impact on HIV incidence.

The conflicting results of these trials have led to confusion among programme managers, researchers and health policy makers. To try and understand these findings, this project was set up between the Mwanza, Rakai and Masaka trial teams and epidemiologists and modellers in London and Rotterdam.

Main findings

The lack of impact of both syndromic management and mass treatment in the Ugandan trials suggests that the contrasting trial findings are explained by differences between the study populations rather than differences between the intervention strategies.

This is supported by reanalysis of trial data. During the trials, reported sexual behaviour was less risky and curable STD prevalences were lower in Rakai and Masaka than in Mwanza.

The simulated impact of each intervention in the population in which it was evaluated showed larger impact of syndromic treatment in Mwanza, than of mass treatment in Rakai or behaviour change with or without syndromic treatment in Masaka, in line with trial findings.

The assessment of the relative effectiveness of each intervention in all three populations showed that, at the time the trials were conducted, any of the intervention strategies would have a larger impact on HIV incidence in Tanzania than in Uganda.

Conclusions

The difference in impact between the trials was due predominantly to differences between the study populations. STD treatment in Rakai and Masaka had little impact on HIV incidence because in those study populations curable STDs accounted for a small proportion of HIV infections. This was due to a reduction in sexual risk behaviour leading to low rates of curable STDs, and a mature HIV epidemic such that most transmission was occurring between stable rather than casual partners in which curable STD were less common.

This study has shown that the effectiveness of intervention strategies may vary depending on the characteristics of populations and the stage of the HIV epidemic. These factors should be considered when planning prevention programmes for a specific population.

Publications

Orroth K, Korenromp E, **White R**, et al. Comparison of STD Prevalences in the Mwanza, Rakai and Masaka Trial Populations: The Role of Selection Bias and Diagnostic Errors. *Sex Transm Infect* 2003,79(2):98-105.

Korenromp E, Bakker R, De Vlas S, et al. HIV dynamics and behaviour change as determinants of the impact of sexually transmitted disease treatment on HIV transmission in the context of the Rakai trial. *AIDS* 2002,16:2209-2218.

Korenromp E, Mondastris S, De Vlas S, et al. What proportion of episodes of gonorrhoea or chlamydia become symptomatic? *Int J STD AIDS* 2002,13(2):91-101.

Korenromp E, Bakker R, De Vlas S, et al. The effect of HIV, behaviour change, and STD syndromic management on STD epidemiology in sub-Saharan Africa: simulations of Uganda. *STI* 2002, Apr 78 Suppl 1:i55-63.

Korenromp E, Bakker R, De Vlas S, Robinson N, **Hayes R**, Habbema J. Can behaviour change explain increases in the proportion of genital ulcers attributable to herpes in sub-Saharan Africa? A simulation modelling study. *Sex Transm Dis* 2002,29(4) Apr:228-238.

Korenromp EL, De Vlas S, Nagelkerke N, Habbema J. Estimating the magnitude of STD cofactor effects on HIV transmission - how well can it be done? *STD* 2001,28(11):613-621.

Korenromp EL, Van Vliet C, **Grosskurth H**, et al. Model-based evaluation of single-round mass STD treatment for HIV control in a rural African population. *AIDS* 2000,14:573-593.

Korenromp EL. Ch 6: Interpreting the Mwanza and Rakai results. In: *From knowledge to practice. STD control and HIV prevention*. Edited by Fransen L: EU HIV/AIDS programme in developing countries; 1999.

Orroth K, Korenromp E, **White R**, et al. Higher risk behaviour and STD prevalences in Mwanza compared to Rakai and Masaka: a possible explanation for outcomes of HIV prevention trials? *AIDS* (In press).

Title	A RANDOMISED TRIAL OF MICRONUTRIENT THERAPY AMONG THAI HIV-INFECTED PATIENTS
Country	Thailand
LSHTM staff	Shabbar Jaffar
Collaborators	<ul style="list-style-type: none">• Sukhum Jiamton, Puan Suthipinittharm (Mahidol University, Bangkok, Thailand)• Suzanne Filteau (ICH)
Funding	Nestlé Foundation
Dates	January 2000 – April 2003

Summary

The aim of this study was to examine whether a comprehensive range of micronutrients that includes vitamins A, B6, B12, C and E and selenium, at doses higher than recommended daily allowance can slow the progression of HIV and reduce the level of HIV-genital shedding. 500 patients were recruited, randomised to receive the intervention or a placebo and then followed regularly for a period of 1-2 years. The main paper from this trial in impact on disease progression and mortality has just published and a PhD thesis by Dr Jiamton was submitted and defended successfully. Analyses for further papers on a) the impact on HIV genital shedding and b) of the association between plasma levels of micronutrients and markers of HIV disease progression and transmission are underway. A follow-up of the study patients to assess whether the beneficial effects of micronutrients might be reproduced over a longer time frame is now underway and this is likely to lead to a further publication.

Publications

Sukhum Jiamton, Jacques Pepin, Reungpung Suttent, Suzanne Filteau, Bussakorn Mahakkanukrauh, Wanna Hanshaoworakul, Pongsakdi Chaisilwattana, Puan Suthipinittharm, Prakash Shetty and **Shabbar Jaffar**. A randomised placebo-controlled trial of the impact of multiple micronutrient supplementation on disease progression and mortality among HIV-1 infected Thai individuals. AIDS 2003; 17: 2461-2469

Sukhum Jiamton. A randomised placebo-controlled trial of the impact of multiple micronutrient supplementation on disease progression and mortality among HIV-1 infected Thai individuals. PhD Thesis, London School of Hygiene and Tropical Medicine, 2003

Title **A RANDOMISED TRIAL TO EVALUATE THE IMPACT OF REGULAR MALARIA CHEMOPROPHYLAXIS ON THE PROGRESSION OF HIV IN LACTATING WOMEN AND THE RISK OF POST-NATAL MOTHER-TO-CHILD TRANSMISSION**

LSHTM staff Shabbar Jaffar

Collaborators • Dr Suzanne Filteau (ICH)
• Dr James Bunn, Professor Bernard Brabin (Liverpool School of Tropical Medicine)

Funding Will be sought from Wellcome Trust

Dates October 2003 – September 2005

Summary

The aim of this trial will be to examine whether malaria prophylaxis might retard the progression of HIV-1 and reduce the risk of HIV-1 transmission in lactating women. Approximately 400 women will be recruited over a period of about 2 years. Various ancillary studies will be conducted, including on adherence to prophylaxis.

Title	PROCESS EVALUATION OF THE COMMUNITY HIV & AIDS PREVENTION STRATEGY (CHAPS)
Country	UK
LSHTM staff	Patrick Branigan, Kaye Wellings
Collaborators	<ul style="list-style-type: none">• Terrence Higgins Trust, London• MESMAC, Yorkshire• Lesbian and Gay Foundation, Manchester• Terrence Higgins Trust , West• Terrence Higgins Trust, South• Big Up• Naz Project• Terrence Higgins Trust, Midlands• The Network• SIGMA Research
Funding	Department of Health
Dates	Currently up until March 2003

Summary

THT co-ordinates the CHAPS partnership which delivers HIV prevention interventions to gay men in six towns and cities in the UK in conjunction with other community based organisations. LSHTM alongside SIGMA provide research input to the programme.

For the last four years a process evaluation has been conducted to help guide the development of the partnership. The final process evaluation report has now been submitted to the Department of Health. It will be widely available as a published report in 2002.

The Sexual Health Programme is now engaged in a study to explore the diffusion network of 'Making It Count' (a theory, ethics and evidence based health promotion strategy to reduce the incidence of HIV infection through sex between men) since its inception. We will look at the role of social modelling in diffusion networks, and how interpersonal communication drives the diffusion process through creating a 'critical mass' of adopters.

Extensive formative evaluation is also carried out on all CHAPS mass-media initiatives with results fed back to the partnership and to the advertising agencies involved. The latest campaign can be viewed on the THT web site (<http://www.tht.org.uk>).

Publications

For full publication list contact SIGMA Research or Will Nutland at the Terrence Higgins Trust.

Title	EVALUATION OF A PARTICIPATORY BEHAVIOUR CHANGE PROGRAMME (STEPPING STONES) FOR HIV PREVENTION IN THE GAMBIA
Country	the Gambia
LSHTM staff	Linda Morison
Collaborators	Matthew Shaw (PI); Katie Paine, Marianne van der Sande, Gijs Walraven, Beryl West, Robin Bailey, Isata Wurie, Michelle Jawo, M E Sowe, Akum Aveika, Keith McAdam (MRC The Gambia); Graham Hart (MRC Sociology Unit, Glasgow)
Funding	MRC

Summary

Stepping Stones is a community level, Participatory Learning and Action (PLA) programme, developed in Uganda for HIV prevention. The Gambian Government, UK Medical Research Council, Action Aid, Gambia Family Planning Association and a local mission collaborated to adapt the programme into an infertility prevention framework in order to discuss sensitive subjects related to reproductive health.

As part of this an STI survey was conducted amongst 15-34 year men and women from 18 villages in a rural area of The Gambia. Following written consent a brief questionnaire was administered and specimens were collected to test for STIs. 1076 participants provided a blood sample. 5% men and 28% of women were HSV2 positive and 2% men and 10% women were TPHA positive. Only 6/1030 urine samples tested positive for chlamydia. Older age, being married and being from the Jola ethnic group were all risk factors for STI. Women were less likely than men to seek treatment for STI symptoms.

An evaluation of Stepping Stones using 2 intervention and 2 comparison villages showed that knowledge of modes of transmission of HIV/STI and levels of risk awareness were raised following the intervention. Dialogue within marriage had increased resulting in a lower occurrence of disagreements and domestic violence. Women reported that they would insist on condom use for sex outside of marriage and even ask their husbands to use condoms for non-marital sex. Diffusion of the programme message had taken place.

Title **THE INTERVENTION WITH MICROFINANCE FOR AIDS AND GENDER EQUITY – IMAGE STUDY**

Country South Africa

LSHTM James Hargreaves, John Porter, Paul Pronyk, Julia Kim, Charlotte Watts, Linda Morison

Collaborators

- Rural AIDS & Development Action Research (RADAR) Programme, Witwatersrand University School of Public Health, Johannesburg, South Africa
- National Department of Health and Welfare, South Africa
- Small Enterprise Foundation (SEF)

Funding

- DFID
- Ford Foundation
- SA National Department of Health
- Kaiser Family Foundation

Dates

Summary

This randomized community intervention trial examines the role of a poverty alleviation programme in reducing vulnerability to both HIV/AIDS and gender-based violence in the rural South African context.

The epidemiology of the HIV epidemic in much of sub-Saharan Africa highlights patterns of social vulnerability that serve to concentrate infection. Many have grouped these into three interconnected categories: (1) poverty and economic underdevelopment; (2) Mobility - including migration, seasonal work, and the social disruption due to war and political instability; and (3) gender inequalities. However, while broadly recognized as contributory to high rates of HIV transmission, there is a serious deficiency in the design and testing of interventions to critically engage issues at this level.

The aim of the Intervention with Microfinance for AIDS and Gender Equity (IMAGE Study) is to develop and evaluate an approach to the prevention of HIV/AIDS which explicitly addresses key social factors driving the epidemic. By integrating and mainstreaming a programme of gender awareness and HIV education into an existing microfinance initiative, IMAGE attempts to operationalize a model for addressing the HIV epidemic which is relevant to settings where poverty and gender inequalities continue to pose a critical challenge to prevention efforts.

The study duration is 2001 through 2004. A detailed qualitative and quantitative design is employed to document changes at the level of individuals, households and the community at large. Biological (HIV incidence), behavioural, social and economic indicators are used to highlight the complexity of factors that interact to shape vulnerability to HIV and gender-based violence in this historically disadvantaged area of South Africa.

Anticipated outputs from this work include:

- Greater understanding of the links between poverty, gender inequalities and HIV/AIDS;
- New evidence documenting the social and health impacts of poverty alleviation and social development programmes;
- An operational model for the implementation of integrated development strategies in the context of high HIV prevalence countries;
- Direct feedback of the process and results of the research to policymakers as part of a South African National Department of Health TB/HIV Pilot Initiative.

References

(Available for Download)

Social Interventions for HIV/AIDS: IMAGE Evaluation Monograph No. 1; IMAGE Intervention Monograph No. 2.

Title	THE IMPACT OF POVERTY REDUCTION/HIV CONTROL PROGRAMME IN SOUTH AFRICA
Country	South Africa
LSHTM staff	Paul Pronyk, John Porter
Collaborators	University of Witwatersrand, Johannesburg, South Africa
Funding	Kaiser Family Foundation
Dates	April 2001 – March 2004

Summary

South Africa is presently experiencing among the highest rates of HIV incidence in the world. In response to the epidemic, the National Department of Health has established four HIV/Tuberculosis Pilot Sites, to implement and assess the effectiveness of an expanded package of district-level clinical services for early diagnosis, care and support for people living with HIV/AIDS. The intent of the Pilot Sites is to develop operational models for HIV control that are able to inform the process of policy formulation and implementation. The Agincourt sub-district of the Northern Province is one such Pilot Site.

The purpose of this initiative is to integrate and evaluate an HIV/AIDS prevention strategy that links clinical interventions to a poverty reduction and empowerment programme. It will also include a poverty-alleviation programme based on a microfinance initiative that facilitates access to credit and savings services among groups of women in poor households.

The research will test the hypotheses that support of clinical services and poverty reduction/empowerment programmes are each important components for reducing a community's vulnerability to HIV infection. Moreover, in communities where interventions operate concurrently, and at multiple levels, there exists the potential for interactions that are reinforcing and synergistic.

Specific objectives:

- To implement and evaluate a package of HIV-related clinical services;
- To demonstrate reductions in poverty, improvements in household welfare, and enhanced economic and social empowerment among women participants in a microfinance programme;
- To demonstrate reductions in high risk behaviour and HIV incidence among 13-35 year old women;
- To generate new knowledge on the interaction between clinical and social interventions at the level of communities, households and individuals.

Title	BRIDGING GAPS BETWEEN PUBLIC AND TRADITIONAL HEALTH CARE SECTORS: A MODEL TO IMPROVE QUALITY PF STI/HIV/AIDS CARE IN SUB-SAHARAN AFRICA
Country	Uganda, Zambia
LSHTM staff	Philippe Mayaud, Ruairi Brugh, James Todd, Monique Oliff
Collaborators	<ul style="list-style-type: none"> • Elisabeth Faxelid, Roy Unge (IHCAR, Karolinska Institutet, Stockholm, Sweden) • Donna Kabatesi (THETA, Uganda) • Freddie Ssengooba (IPH, Makerere University, Uganda) • Phillimon Ndubani (INESOR, University of Zambia, Zambia) • Rodney Vongo (THPAZ, Zambia)
Funding	European Commission (EC)
Dates	2002 – 2006

Summary

The general objective of this research is to develop and evaluate innovative strategies to create mutual understanding and increased dialogue and collaboration between public and traditional health care providers in Uganda and Zambia. The purpose is to improve the quality and increase the uptake of STI/HIV/AIDS health care services, focusing particularly on the humanity of patient/provider interactions and effectiveness of public (preventive) health services in both sectors. By humanity is meant a) consumer satisfaction in relation to the care they receive, and b) quality of the communication, empathy, and sensitivity of providers. Public health dimensions will include promotion and uptake of key STI/HIV/AIDS related health services such as condom use, partner notification, voluntary counselling and testing (VCT) for HIV, awareness of STI symptoms and importance of STI treatment, and better access to quality services through both sectors.

A process oriented, country-specific intervention will be designed, implemented and evaluated. The intervention will build on earlier work and on-going activities related to collaboration between the traditional and public sectors in the two countries. Strategies to be agreed in the preliminary phase and tested through the intervention and evaluation will include: joint and separate training activities, interactive group discussions (involving public and traditional health care providers), and the development of provider peer influencing networks (PINs). Process indicators which will be developed to evaluate the intervention will, for example, assess: attitudes towards the opposite type of provider and towards collaboration, meetings/interactive sessions involving public and traditional health care providers, and referrals between the sectors. Outcome indicators (in both sectors) will assess: patient satisfaction with STI/HIV/AIDS care received, the delivery of health promotion activities, and uptake of the above mentioned key STI/HIV/AIDS related health services. The same indicators will be assessed in a quasi-experimental control arm to monitor secular effects.

Progress

The project started in September 2002 with review of practices regarding intersectoral collaboration in both countries, stakeholder consultations, and the collection of key information for site selection. This was followed by a large workshop in January 2003 which decided on research sites and methodological tools. The choice of districts was 'rural' for Uganda and 'urban' for Zambia, reflecting the reality of life of these two countries, and the diversity of traditional healers practices throughout Africa.

A baseline study was conducted in 2 sub-districts in each country (one will become intervention site, the other one control) from April-July 2003. This consisted of:

1. At community level: focus group discussions, community members interviews (random sample).
2. At biomedical sector level: interviews with key health managers in district; interviews of staff at all sub-district clinics; observation of consultations in facilities (with emphasis on STI/RH/HIV patients); exit interviews for patients; mystery STD patients and HIV VCT patients; review of registers (ANC, STI, VCT, OPD).
3. At traditional healer (TH) sector level: mapping of all TH; interviews of TH; observation of consultations in shrines (with emphasis on STI/RH/HIV patients); exit interviews for patients.

The project is now gathering interest from various stakeholders about the range of activities and form that collaboration between the two sectors can take over the next two years, and a workshop will be organised early 2004 to review the results of the baseline research and to develop the intervention and basic monitoring tools.

Publications

Unge R, **Brugha R**, Faxelid E, Kabatesi D, **Mayaud P**, Ndubani P, Ssengooba F, Vongo R. Bridging gaps between public and traditional health care sectors – testing a model to improve quality of STI/HIV/AIDS care in Sub-Saharan Africa. Abstract LbPp2201. XIVth International AIDS conference, Barcelona, Spain, July 7-12, 2002.

A website has been setup for this project and reports of activities can be consulted:

www.phs.ki.se/ihtar/bg/

Title	EVALUATION OF ANTIRETROVIRAL THERAPY IMPLEMENTATION FOR HIV-INFECTED EMPLOYEES OF ANGLO AMERICAN GROUP COMPANIES
Country	South Africa
LSHTM staff	Alison Grant, Katherine Fielding, Lilani Kumaranayake
Collaborators	Aurum Health Research, South Africa
Funding	Aurum Health Research
Dates	October 2002 – September 2005

Summary

Objectives

To evaluate ART provision in the mining industry and other industrial settings with respect to key feasibility issues and clinical outcomes.

Methodology

Observational cohort

4.4 Specific interventions against HSV, BV, syphilis

Title	ANTI-HERPETIC TREATMENT WITH SYNDROMIC MANAGEMENT OF GENITAL ULCER PATIENTS IN AFRICA: CLINICAL AND BIOLOGICAL EVALUATION ON HIV-1 AND HSV-2 GENITAL SHEDDING
Countries	Central African Republic, Ghana, France, UK
LSHTM staff	Philippe Mayaud, Helen Weiss, David Mabey, Richard Hayes
Collaborators	<ul style="list-style-type: none"> • David Brown (EVRL/PHLS, Colindale) • Laurent Belec (Hôpital Européen Georges Pompidou and INSERM U430, Paris, France) • Gerard Gresenguet (CNRMST, Bangui) • Khonde Nzambi (WAPTCAS, Ghana) • Jacques Pepin (Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke, Canada)
Funding	<ul style="list-style-type: none"> • Agence Nationale de Recherche sur le SIDA (ANRS), France • GlaxoSmithKline, R&D Department, UK
Dates	April 2002 – March 2004

Summary

Rationale

Increasing evidence suggests that genital infection with HSV-2 is likely to represent an important cofactor involved in HIV acquisition and/or transmission, either through clinical episodes of genital herpes or asymptomatic genital HSV shedding. The definite proof of this concept has never been made through randomised controlled trials.

There are broadly three possible interventions to control HSV infection:

1. Primary prevention through behaviour modification, use of condoms or HSV vaccination;
2. Treatment of clinical episodes (episodic therapy);
3. Suppression of HSV shedding (suppressive therapy).

Study design

Building on previous work on HSV-2 and HIV shedding in Bangui, the proposed project is a randomised placebo-controlled, double-blind, multicentric therapeutic trial evaluating the addition of antiherpetic treatment (episodic therapy by acyclovir for 5 days) to the standard syndromic management (SM) of genital ulcers in Africa, in terms of impact on the frequency and quantity of genital viral shedding of HIV and HSV-2.

The trial will also determine the conditions of adherence to treatment, the frequency of side effects and the cure rates of genital ulcers achieved by SM +/- acyclovir and by HIV serostatus.

The trial started in 2003.

Title	RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF ACYCLOVIR FOR THE REDUCTION OF HIV ACQUISITION AND SHEDDING AMONG HIGH-RISK HSV-2 SEROPOSITIVE WOMEN IN SOUTH AFRICA
Country	South Africa
LSHTM staff	Philippe Mayaud, Helen Weiss
Collaborators	<ul style="list-style-type: none"> Sinead Delany (PhD student), Helen Rees (RHRU, Baragwanath Hospital, Johannesburg, South Africa) Laurent Belec (Hopital Europeen Georges Pompidou and INSERM U430, Paris, France) Connie Celum (University of Washington, USA; HPTN039)
Funding	<ul style="list-style-type: none"> Wellcome Trust (submitted) NIH (larger study) DFID Knowledge Programme on HIV/AIDS & STIs
Dates	2002 – 2006

Summary

Rationale

Increasing evidence suggests that genital infection with HSV-2 is likely to represent an important cofactor involved in HIV acquisition and/or transmission, either through clinical episodes of genital herpes or asymptomatic genital HSV shedding. The definite proof of this concept has never been made through randomised controlled trials.

There are broadly three possible interventions to control HSV infection:

1. Primary prevention through behaviour modification, use of condoms or HSV vaccination;
2. Treatment of clinical episodes (episodic therapy);
3. Suppression of HSV shedding (suppressive therapy).

Study design

A large multicentre phase III, randomized, double-blind, placebo-controlled trial of acyclovir (suppressive therapy) for the reduction of HIV acquisition among high-risk HSV-2 seropositive, HIV seronegative individuals will be set up by the University of Washington (USA) with NIH funding in several sites outside the US. The RHRU will be one of the participating sites.

Nested within this larger study, and as part of her PhD studies, Sinead Delany (RHRU/LSHTM) will conduct a double blind placebo controlled RCT of HSV suppressive therapy to determine the efficacy of twice daily acyclovir suppressive therapy on the frequency and quantity of HIV viral shedding among HSV-2 seropositive women who are co-infected with HIV and not requiring antiretroviral therapy.

Secondary outcomes will include:

1. Measurement of the effect of anti-herpetic suppressive therapy on the frequency and quantity of subclinical genital HSV2 viral shedding in HSV2 seropositive women who are co-infected with HIV;
2. Evaluation of the performance of various HSV serological assays;
3. Identification of factors influencing adherence to anti-herpetic suppressive therapy in a population of South African women.

The trials will start in 2004.

Title	IMPACT OF EPISODIC ACYCLOVIR THERAPY ON ULCER DURATION AND HIV SHEDDING FROM GENITAL ULCERS AMONG MEN IN SOUTH AFRICA
Country	South Africa
LSHTM staff	Sarah Hawkes, Helen Weiss, David Mabey
Collaborators	<ul style="list-style-type: none"> • Gabriela Paz-Bailey, Caroline Ryan, Ron Ballard, Lauri Markowitz (CDC) • Henry Koornhof (NICD, South Africa)
Funding	US Centers for Disease Control and Prevention
Dates	October 2003 – December 2005

Summary

We propose to conduct a randomized placebo-controlled trial of the effect of HSV-2 episodic therapy on symptomatic herpes and on HIV shedding from genital ulcers. This study will help answer the question if acyclovir therapy for herpes should be added into the syndromic management of genital ulcer disease. Acyclovir has an acceptable profile for widespread STD treatment and is now relatively inexpensive and well-tolerated. Given that HSV-2 is the leading cause of GUD in the developing world, this approach could have a great public health importance, by providing a safe, acceptable, and cost-effective method to treat genital ulcer disease and potentially reduce HIV transmission. If acyclovir therapy reduces HIV shedding, its incorporation into syndromic management would provide an effective way to scale it up as a public health intervention.

The study will be conducted among miners in Carletonville, South Africa. This population is at high risk of HIV/STD infection and will be easily accessible to ensure compliance with medication, counselling and for follow-up sessions. Gabriela Paz-Bailey will conduct her PhD based on this study.

The *aims* of the study were:

- To measure the efficacy of acyclovir episodic therapy on reducing the duration and severity of an HSV-2 clinical outbreak;
- To measure the effect of acyclovir episodic therapy on HIV and HSV-2 shedding from genital ulcers;
- To describe treatment seeking behaviours among men in relation to sexually transmitted diseases;
- To model the impact of and estimate the cost-effectiveness of providing episodic herpes treatment as part of syndromic management.

Main results

Study is in preparation.

Publications

None.

4.5 New STI diagnostic tests

Title	FIELD EVALUATION OF SIMPLE POINT-OF-CARE TESTS FOR SYPHILIS
Country	Tanzania, India
LSHTM staff	David Mabey, Dean Everett
Collaborators	<ul style="list-style-type: none">• WHO• TDR (STD Diagnostics Initiative)• NIMR, Mwanza, Tanzania
Funding	SDI
Dates	2001 – 2004

Summary

Programme staff and collaborators in Mwanza, Tanzania submitted an application to run field and laboratory sites for the evaluation of new rapid, simple point-of-care tests for syphilis on behalf of the WHO STD Diagnostics Initiative. These were considered 2001 and the site was among the six selected. There are now several dipstick-type serological tests for syphilis on the market, some of which do not require separation of serum. None has been independently evaluated, and none is FDA approved. We are evaluating the tests for the screening of antenatal clinic populations.

Title	CASE MANAGEMENT OF REPRODUCTIVE TRACT INFECTIONS IN INDIA: AN ANALYSIS OF CLINICAL PROTOCOLS AND COSTS
Country	India
LSHTM staff	Sarah Hawkes
Collaborators	<ul style="list-style-type: none"> • Suneeta Mittal, Dr R.M. Pandey (All India Institute for Medical Sciences, New Delhi, India) • Jorge Tolosa (Thomas Jefferson University, USA) • Dr Shally Awasthi, Dr Vinita Das (King George's Medical College, Lucknow, India) • Dr Susan D. Foster (Boston University, USA) • Dr Pisake Lumbiganon (Khon Kaen University, Khon Kaen, Thailand) • Dr Manorama Purwar (Nagpur Medical College, India) • Dr Sheela Shenoy (Medical College, Trivandrum, India)
Funding	EU via Population Council, India
Dates	May 2003 – November 2004

Summary

This project aims to review existing national and international guidelines for management of reproductive tract infections (RTIs) management and to validate the effectiveness of these guidelines in terms of clinical management and costs in four sites in India. We will evaluate the guidelines with respect to their levels of under treatment and/or over treatment of common infections, and look at the management costs associated with using these guidelines. The results will be used to develop protocols for management, which can be used in a variety of settings which may be expected to be found in India. In addition, we aim to incorporate an evaluation of rapid diagnostic tests for the most common sexually transmitted infections and to compare the costs of these diagnostic tests with the costs of using clinical guidelines alone. We will then carry out a cost-effectiveness analysis to determine the most cost-effective management strategy for symptomatic women complaining of RTI symptoms in primary health care settings in India. We will study which are acceptable strategies for management of partners of women who are diagnosed with STIs.

The *aims* of the study are:

1. Determine the prevalence and aetiology of reproductive tract infections among symptomatic women with vaginal discharge, genital itching and/or burning sensation attending for care in four areas in India;
2. Determine the demographic and behavioural characteristics of women (including their perceptions of partners' risks) found to have reproductive tract infections among this population;
3. Determine the relative success of different flowcharts for the management of women complaining of vaginal discharge in different settings in India;
4. Assess the cost-effectiveness of implementing each of these flowcharts for standardized RTI case management;
5. Address issues of the acceptability of different types of partner management.

Main results

Study is recruiting women in New Delhi; funding for three further sites being sought.

Publications

None.

4.6 Surveillance and Monitoring

Title	SEXUAL BEHAVIOUR AND CONDOM USE: MEASUREMENT ISSUES & DATA QUALITY
Country	Tanzania, Multi-country analyses
LSHTM staff	Emma Slaymaker, Basia Zaba, John Cleland, Oliver Hoffman
Collaborators	<ul style="list-style-type: none">• Ties Boerma (WHO)• Sharon Weir (Measure Evaluation, UNC)• Michel Carael (UNAIDS)
Funding	<ul style="list-style-type: none">• WHO• UNAIDS• UNICEF• Measure Evaluation

Dates

Summary

The focus of this work is on developing robust methodologies for measurement and analysis and estimating the validity of self-reported data by applying consistency checks, including comparison of behavioural and biological indicators

An analysis of a closed subgroup of partnership reports obtained from males and females in a sexual network study in the TANESA cohort, Tanzania has shown that although females under-report sexual partnerships to a larger extent than males, they do so consistently, whereas males may sometimes exaggerate the extent of their sexual activity, so that female reported behaviour is in fact more closely linked to HIV infection as an outcome.

A multi-survey analysis was conducted to answer the question: "By how much would be incidence of unintended pregnancies rise if couples switched from highly effective hormonal methods of contraception to the less effective condom?" The answer was "very little" and the reason for this counter-intuitive result was the fact that a large majority of unintended pregnancies in developing countries - even those where the prevalence of use is relatively high - stem from non-use of any method rather than contraceptive failure.

In September 2003, we convened a international workshop on the measurement of sexual behaviour in developing countries. Details may be found on <http://www.lshtm.ac.uk/cps/events/sexmeeting/>. A special issue for the journal Sexually Transmitted Infections is in preparation.

Publications

Slaymaker E, Zaba B. (in press) "Measurement of Condom Use as a Risk Factor for HIV Infection" in Reproductive Health Matters.

Nnko S, Boerma JT, Urassa M, Mwaluko G, **Zaba B.** (in press) Secretive females or swaggering males? An assessment of the quality of sexual partnership reporting in rural Tanzania. Social Science and Medicine.

Zaba B, Boerma T, Pisani E. Estimation of levels and trends in age at first sex using survival analysis. Measure Evaluation working paper, WP-02-51, March 2002.

Ali, M, **Cleland J,** Shah I. (in press) Condom use within marriage: a neglected HIV intervention. Bulletin of the World Health Organisation.

Title	IDENTIFICATION OF APPROPRIATE INDICATORS AND DEVELOPMENT OF MONITORING AND EVALUATION SYSTEM FOR UNAIDS
Country	Burma (Myanmar)
LSHTM staff	Megan Douthwaite
Collaborators	
Funding	UNAIDS
Dates	2003

Summary

The overall objective of the project is to identify appropriate indicators to monitor and evaluate UNAIDS funded activities that are implemented through a variety of partners, including NGOs, government, and UN agencies. The project will also design a data collection system to be implemented by UNAIDS in Burma to collate and analyse these indicators.

Chapter 5. Prioritisation and implementation of HIV/AIDS and STI prevention and care policies

5.1 Policy transfer

Title	INTEGRATION OF STI PREVENTION AND CARE INTO REPRODUCTIVE HEALTH SERVICES IN TANZANIA: AN ANALYSIS OF BARRIERS AND OPPORTUNITIES
Country	Tanzania
LSHTM staff	Philippe Mayaud, Monique Oliff (PhD student) Ruairi Brugha, Jim Todd, Louisiana Lush (Advisors)
Collaborators	<ul style="list-style-type: none"> • Vera Pieroth, Daraua Bukunya (AMREF, Tanzania) • Ave-Maria Semakafu (Muhimbili University of Clinical and Health Sciences, Dar Es Salaam, Tanzania)
Funding	DFID (Innovations Grant)
Dates	June 2000 – June 2002 (completed)

Summary

Operational study aiming at better understanding the barriers and opportunities at the national, regional district and delivery levels that inhibit or promote the provision of comprehensive reproductive health services and STI care. The project was conducted by a PhD student (Monique Oliff) for her research project. The PhD was awarded in August 2002.

The study used multi-disciplinary approach and consisted of:

- A review of national policy documents;
- A stakeholder analysis and political mapping;
- An analysis of service provision including interviews and observations in 9 randomly selected health facilities in 3 regions;
- In-depth interviews with clients of reproductive services and health providers (including a sample of alternative care providers), and focus group discussions with community members.

Main results/outcomes

Many areas of opportunities to improve the delivery of comprehensive reproductive health services to include STI prevention and care lie in: (1) Existing pre-service training infrastructure; (2) Workforce management and maximisation of the potential of existing staff; (3) Workforce supervision, role of district management teams; (4) Community responsibilities; (5) Involvement of men as clients; (6) Opening of policy arena to the influence of civil groups and NGOs.

A feedback workshop with key stakeholders was held in Tanzania using a very innovative participatory method involving the subjects of the research from the community to have dialogue with the national policy-makers.

Publications

Oliff M. Integration of STI services into reproductive health services in Tanzania: an operational analysis of and opportunities, barriers and achievements. DrPH thesis, LSHTM, University of London, August 2002.

Oliff M, **Mayaud P**, Brugha R, Semakafu A-M. Integrating Reproductive Health Services in a Reforming Health Sector: The Case of Tanzania. *Reproductive Health Matters* 2003; **11 (21)**: 37-48.

3 other papers in preparation

Conferences/other

Oliff M, Mayaud P, Bukunya D, et al. Integration of STI prevention and care into reproductive health services in Tanzania: an analysis of barriers and opportunities for comprehensive, quality reproductive health services. Abstract WePeD6418. XIVth International AIDS conference, Barcelona, Spain, July 7-12, 2002.

Oloff M, Mayaud P, Pieroth V, et al. 'Men as Men' – the reproductive health demands of men in rural and roadside settlements in Tanzania: What are we waiting for? Abstract TuPeF5230. XIVth International AIDS conference, Barcelona, Spain, July 7-12, 2002.

Oloff M. "Corn, Cattle, Coconuts and Condoms". Video of the community participants and feedback workshop.

Title	INTEGRATION OF STI SERVICES WITH PRIMARY HEALTH CARE
Countries	Global
LSHTM staff	Louisiana Lush, Susannah Mayhew, Gill Walt, John Cleland, Justin Parkhurst
Collaborators	
Funding	Wellcome Trust
Dates	

Summary

Ongoing analysis of policies to integrate components of reproductive health care into primary health care. Overview of policy developments to date and investigation of the role of international donors in creating barriers and opportunities for integration of services in low income countries.

Publications

Lush, L. (2002). Service integration: an overview of policy developments. *International Family Planning Perspectives* **28**(2): 71-76.

Mayhew, S., G. Walt, L. Lush and **J. Cleland** (2003). Donor involvement in reproductive health: saying one thing and doing another? *International Journal of Health Services*.

Title	HIV POLICY IN CONTEXT
Countries	Uganda, South Africa, Thailand, Botswana, El Salvador, Guatemala
LSHTM staff	Louisiana Lush, Justin Parkhurst, Sripin Tantivess, Nicole Klynman, Gabriel Brat.
Collaborators	<ul style="list-style-type: none"> • Health Economics and Financing Programme (HIV Tools Team) • Health Systems Research Institute, Thailand • Population Services International, El Salvador • African Comprehensive HIV/AIDS Partnership, Botswana
Funding	<ul style="list-style-type: none"> • DFID • WHO • PSI • Marshall Scholarship
Dates	2002 - 2003

Summary

A programme of work looking at how HIV interventions have developed in particular political contexts, and at the processes which trigger major policy innovations. A framework for understanding political context has been developed which goes beyond bland concepts of 'political leadership' and 'capacity building' and compares developments in STI care and behaviour change interventions in Uganda and South Africa. New projects are looking at:

1. Processes involved in agenda setting for universal antiretroviral therapy in Thailand;
2. Relationship between research and policy for HIV;
3. Assessment of international NGO advocacy for access to antiretroviral therapy and its relationship to national policy;
4. Political and health systems context of HIV interventions in Botswana and;
5. Interactions between state and NGOs in delivery of behaviour change interventions in Central America.

Publications

Parkhurst, J. and **L. Lush** (Submitted) Policy transfer and the political environment of HIV: lessons from a comparison of Uganda and South Africa. *Social Science and Medicine*.

Title	ASSESSMENT OF THE IMPACT OF PUBLIC PRIVATE PARTNERSHIPS ON THE HEALTH SYSTEM IN UGANDA
Country	Uganda
LSHTM staff	Louisiana Lush
Collaborators	Institute for Health Sector Development
Funding	<ul style="list-style-type: none">• Initiative for Public Private Partnerships in Health• DFID
Dates	January – October 2003

Summary

Assessment of the impact of global public private initiatives for drug donations or price reductions on the health system of low income countries, with a pilot study in Uganda. Focussed on four tropical disease drug donation programmes (lymphatic filariasis, ochocerciasis, leprosy and sleeping sickness) and three HIV/AIDS programmes (Viramune, Diflucan and the UNAIDS Accelerated Access Initiative).

Publications

Lush, L. (2001) *Public-private partnerships and guaranteeing drug delivery through health systems: issues needing further research*. Geneva: Annual Conference of the Global Forum for Health Research.

Caines, K., J. Bataringaya, **L. Lush**, G. Murindwa and H. Njie. (2003) *Impact of public-private partnerships addressing access to pharmaceuticals in low income countries: Uganda pilot study*. Geneva, Report prepared for the Initiative on Public-Private Partnerships for Health and the UK Department for International Development

Title	BRIDGING BARRIERS WITH THE NON-FORMAL PRIVATE HEALTH SECTOR: IMPROVING QUALITY OF CARE FOR REPRODUCTIVE TRACT / SEXUALLY TRANSMITTED INFECTIONS (RTIS/STIS) IN NORTH INDIA
Country	India (states: Uttar Pradesh and Uttaranchal)
LSHTM staff	Meenakshi Gautham (PhD student), Ruairi Brugha, Heiner Grosskurth (LSHTM study advisors) Gill Walt, Karina Kielmann, Helen Weiss (PhD Supervisory Committee members at LSHTM)
Collaborating	<ul style="list-style-type: none"> Population Council, India Dr. Rajesh Singh, Dr. Deoki Nandan (Garhwal Community Development and Welfare Society, Christian Hospital, Chamba, Tehri Garhwal, India)
Funding	<ul style="list-style-type: none"> Population Council-HIV/STI Prevention and Care Research Programme, India, through a grant from the European Commission Ford Foundation, India

Dates June 2002-January 2004

Summary

The study first qualitatively explores the dynamics of care seeking and provision for RTIs/STIs at the primary point of care seeking in rural areas– most frequently in the non-formal private health sector. In the following quantitative phase, systematic assessments of quality of care for RTIs/STIs, provided by rural private practitioners, are carried out to determine the appropriateness of care provided in relation to (i) patient's needs and preferences, (ii) established clinical treatment guidelines and (iii) the aetiology of presenting complaints (biological / psychological). A stakeholder analysis explores the feasibility of policies conducive to improving quality of care by rural practitioners. Findings will be used to develop and later pilot an intervention to improve quality of care.

Objectives

To assess the quality of care available from rural private practitioners to men and women suffering from symptoms suggestive of RTIs/STIs; to identify barriers to improving quality of care; and to develop (and later pilot) an intervention to improve the quality of RTI/STI care at the community level.

Methodology

The study consists of a series of qualitative and quantitative sub-studies and a stakeholder analysis. The qualitative phase uses free-listing (of symptoms), followed by focus group discussions and a household survey of men and women to explore health care seeking and 'quality of care' opinions and needs. The quantitative phase is marked by clinic observations, provider interviews and facility assessments, patient specimen collection and lab investigations, and an exit interview using a psychological screening instrument. These two study phases will be supplemented by a stakeholder analysis, involving policy makers at district, state and national levels. Findings will be used to develop an intervention in collaboration with local stakeholders.

Results

Project initiated in June 2002, data collection in process and preliminary results expected by April 2003.

Publications

To be decided.

Title **DEMOGRAPHIC IMPACTS OF AIDS****LSHTM staff** Basia Zaba, Ian Timæus, John Blacker, Carine Ronsmans, Jimmy Whitworth**Collaborators** UN reference group on estimates and projections of HIV/AIDS; Griffith Feeney and Tim Brown (University of Hawaii); Geoff Garnett, Nicholas Grassly, James Lewis and Roy Anderson (Imperial College); Kholoud Porter (MRC); Alan Whiteside (UEA and HEARD, Univ of Natal); Ties Boerma (WHO); Marie-Louise Newell (ICH); Patrick Heuveline (Univ of Chicago)**Funding** UNAIDS, UN Population Division, NIH, DfID, WHO, Wellcome Trust**Summary**

Through ongoing work with the reference group, we review the empirical evidence for the demographic impact of AIDS, examining impacts on mortality, fertility, population growth, orphanhood, and family structure. The remit of this group is also to evaluate current national estimates of prevalence and incidence, and to advise the UN system on projection methodology.

A non-age structured model for smoothing the prevalence data from ante-natal clinics to produce current prevalence estimates and to make short term forecasts has been developed by the reference group after the meeting in la Mainaz (Jan 2001). A report describing the model is available on the reference group web site (<http://www.epidem.org/publications.htm>). It is currently being used to produce the estimates and projections for the next UNAIDS global report. The methods and the empirical data which form the basis of various components of this model are described in a special edition of AIDS published for the Barcelona conference of IAS, 2002.

In a separate initiative arising from the October 2000 reference group meeting in Frascati, Timæus and Grassly developed a model for producing estimates and projections of the paternal orphans and double orphans, as well as maternal orphans, that are resulting from the epidemic. The method was used to produce the 'Children on the Brink' estimates of orphans in 2002 and a series of three journal papers describing the approach and the implications of the resulting estimates have been submitted for publication.

An international conference on demographic and socio-economic impacts of HIV was organised in March 2003 in Durban, South Africa, with the collaboration of HEARD at the University of Natal, Durban, funded by NIH and the Wellcome Trust. A special Issue of AIDS is being published with review articles on direct and indirect evidence of the impacts of HIV on adult and child mortality; fertility, family structure and orphanhood impacts, and an assessment of the performance of official UNAIDS projection models.

Publications

UNAIDS reference group on estimates, modelling and projections. Improved methods and assumptions for estimating the HIV/AIDS epidemic and its impact. AIDS 2002, 16:W1-W14

Zaba B, Boerma T and Fontanet, A eds. Empirical Evidence for the Socio-Demographic Impact of AIDS, forthcoming special issue of AIDS, 2003

Zaba B, Whiteside A and Boerma JT. "Demographic and socio-economic impact of the AIDS epidemic: taking stock of the empirical evidence". Accepted for publication in AIDS, September 2003

Porter K and Zaba B. "The empirical evidence for the impact of HIV on adult mortality in the developing world: data from serological studies". Accepted for publication in AIDS, September 2003

Zaba B. AIDS. Entry in Encyclopedia of Population, ed. Geoff McNicoll and Paul Demeny. Macmillan, New York, 2003. ISBN 0-02-865677-6; pp. 37-43

Hosegood, V., Vanneste, A-M. and Timæus, I. M. Levels and causes of adult mortality in rural South Africa, Accepted for publication in AIDS, October 2003

Grassly, N. C. and Timæus, I. M. Methods to estimate the number of orphans due to AIDS and other causes in sub-Saharan Africa, submitted to J AIDS

Title	HIV IMPACT ON FERTILITY – CAUSES, CONSEQUENCES AND MEASUREMENT ISSUES
Countries	Uganda and Malawi
LSHTM staff	Basia Zaba, Susan Hunter, Judith Glynn, Jimmy Whitworth, Emma Slaymaker
Collaborators	Ties Boerma (WHO); Lucy Carpenter, Nicola Terceira (Oxford University); Simon Gregson, James Lewis (Imperial College); Jessica Nakiyinge (MRC Masaka); Mark Urassa (TANESA), Constance Nyamukapa (Manicaland project)
Funding	DFID, UN Population Division

Summary

There are several on-going projects in this research area, all of them concerned with identifying the HIV-associated factors (behavioural and biological) which cause the fertility of HIV positive women to differ from that of their HIV negative counterparts, and in exploring how these differences affect HIV prevalence measures based on ante-natal surveillance. A common aim is to produce an algorithm for adjusting prevalence measures based on monitoring pregnant women to make them representative of prevalence in the general female population in the child bearing ages.

A “proximate determinant” model of sexual behaviour and biological factors which determine age specific fertility and infection risk has been developed and published by the UN Population Division, subsequent to its presentation at a meeting on completing the fertility transition. Our links with the TANESA project (Tanzania), the MRC programme in Masaka (Uganda) and the Manicaland project (Zimbabwe) have allowed us to test model predictions against empirical data, and to develop practical methods for adjusting data and interpreting biases. The model has been calibrated to represent countries at different stages of the fertility transition, and the adjustment procedure based on the model was recently validated in two new data sets.

Publications

Terceira N, Gregson S, Zaba B and Mason P. On the contribution of HIV to fertility decline in rural Zimbabwe. *Population Studies*, 57(2):149-164, 2003

Gregson S, Zaba B, Hunter SC. The Impact of HIV 1 on Fertility in sub-Saharan Africa: Causes and Consequences. *UN Population Bulletin*, special issue on “Completing the fertility transition” 2003. Also published electronically: <http://www.un.org/esa/population/publications/completingfertility/completingfertility.htm>

Hunter S, Isingo R, Boerma JT, Urassa M, Ng'weshemi J, Zaba B. Association between HIV and fertility in a cohort study in Tanzania. *J. BioSoc Sci*, 35:189-199 2003.

Zaba, B & Gregson S. HIV and Fertility. Entry in *Encyclopedia of the Social Sciences*, ed Jan Hoem et al. Elsevier.

Title	HIV AND CHILD MORTALITY
Countries	Uganda, Malawi
LSHTM staff	Basia Zaba, Andy Sloggett; Judith Glynn, Sian Floyd, Mia Crampin, Milly Marston
Collaborators	MRC centre Masaka, Uganda TANESA study, Tanzania Karonga Prevention Study, Malawi Marc Artzrouni, University of Pau, France
Funding	UNICEF, Measure Evaluation, UNAIDS, UN Population Division

Summary

This study has two main aims, each with several subsidiary research questions:

1. To ascertain current levels of child mortality in populations affected by HIV and assess the contribution of HIV to the burden of child mortality;
2. To propose methods for correcting the estimates of child mortality obtained using birth history and indirect approaches, which are subject to bias in the presence of HIV, due to a high correlation between maternal and child mortality.

Analyses of the impact of HIV on child mortality have been prepared with the help of collaborators working at for each site, focussing on the relationship between maternal HIV infection, maternal survival and child mortality. They have been presented at project workshops, at the international IAS conference in Barcelona in 2002, and have now been published in academic journals. A meta analyses of the combined individual level data has been undertaken and submitted for publication. A paper proposing a new method for estimating HIV attributable mortality at national level was presented at a meeting on HIV mortality organised by the UN Population Division in New York in September 2003. A method for deriving “net” HIV mortality rates for infants and children, allowing for different background mortality levels has been devised, and will be presented to the next meeting of the UNAIDS reference group on estimates and projections.

The most important research finding so far, is that maternal mortality has a large effect on child survival that appears to be independent of maternal HIV status. Child mortality is increased approximately by a factor of five in the year immediately following or preceding a mother’s death. Mortality rates for children of HIV positive mothers are about three times those of HIV negative mothers. The association between maternal and child mortality causes five-year retrospective reports on child mortality by HIV positive mothers to under-estimate the true rates by around 8% in populations where HIV prevalence in females is around 10%.

A micro-simulation model has been constructed to generalise the findings about the extent of the reporting bias in epidemics with different levels, trajectories and maturity, a paper based on this model we be prepared in due course.

Publications

Zaba B, Marston M & Floyd S. "The effect of HIV on Child Mortality Trends in sub-Saharan Africa". Published electronically at <http://www.un.org/esa/population/publications/adultmort/Adultmortality.htm> and accepted for publication in UN Population Bulletin, 2004.

Nakiyingi, Jessica S; Bracher, Michael; Whitworth, James AG; Ruberantwari, Anthony; Busingye, June; Mbulaiteye, Sam M; Zaba, Basia. Child survival in relation to mother's HIV infection and survival: evidence from a Ugandan cohort study. AIDS. 17(12):1827-1834, August 15, 2003.

Ng'weshemi J, Urassa M, Isingo R, Mwaluko G, Ngalula J, Boerma T, Marston M, and Zaba B. HIV impact on mother and child mortality in rural Tanzania. J.AIDS, 33(3):393-404, 2003.

Crampin A, Floyd S, Glynn J, Madise N, Nyondo N, Khondowe M, Njoka C, Kanyongoloka H, Ngwira B, Zaba B, Fine P. The impact of HIV on the mortality and well-being of children in rural Malawi. AIDS, 17:389-398, 2003.

Zaba B, Marston M, Nakiyingi J, Whitworth J, Ruberantwari A, Urassa M, Issingo R, Mwaluko G, Crampin A, Floyd S and Nyondo A. HIV and mortality of Mothers and Children: evidence from cohort studies in Uganda, Tanzania and Malawi. Submitted to Epidemiology, 2003.

Title	THE ROLE OF MOBILITY IN THE SPREAD AND CONTROL OF STD AND HIV
Countries	Tanzania and Zimbabwe (case studies) other African countries (secondary analyses); Nepal, India (cross border study)
LSHTM staff	Basia Zaba, Richard White, Steve Mills, Jim Todd, Karina Kielmann, John Cleland
Collaborators	Dik Habbema, Helene Voeten Erasmus University Rotterdam; Mark Urassa, Raphael Issingo (TANESA project, Tanzania); Constance Nyamakupo (Manicaland project, Zimbabwe); Simon Gregson, Imperial College, London
Funding	EC, FHI

Summary

Two projects are reported under this heading: the African project has been funded by the EC since 2000, with Erasmus University as the lead partners; the Nepal / India project is a PhD research project done in collaboration with FHI.

The aim of the first project is to study the impact of mobility on the spread of STD/HIV and the relative effectiveness of different interventions in settings with different mobility patterns. A detailed data analysis will be undertaken of mobility data from two African study areas (one in Tanzania, one in Zimbabwe), followed by simulation modelling – it is hoped that this modelling exercise will yield results which will help in the interpretation of currently observed epidemic patterns, and to help plan strategies to increase the effectiveness of interventions in highly mobile populations.

Preliminary data analysis has been completed of mobility data already available for the two study sites, and an abstract was presented at the IAS conference in Barcelona in 2002 based on the data from the Kisesa site in Tanzania. This showed that after allowing for age, current residence and marital and non-marital partnership patterns, mobility remained an important explanatory variable with respect to HIV incidence for both males and females.

We have also completed a review of information on mobility contained in DHS data from all African surveys completed in the 80s and 90s. This ecological analysis showed that mobility differences between West African countries on the one hand, and Eastern and Southern African countries on the other, could account for 71% of the observed inter-country variation in the prevalence of HIV.

The study of Nepali circular migration to India study seeks to determine the role of male migration, associated risk behaviours, and factors which may mediate those risks in the spread of HIV and other STI in rural Nepal. It consists of two cross-sectional integrated biologic and behavioural surveys of HIV, other selected STIs, risk behaviours, and potential demographic correlates conducted in a population-based sample of men in a rural high migrating community in the Himalayan foothills of Far Western Nepal and in a sample of migrants and non-migrants in a district bordering on India. A standardised and pre-tested questionnaire containing questions on migration behaviour, past and current sexual behaviours at origin and destination, social support, and socio-demographic characteristics was used. The migrants were also requested to provide blood and urine samples for the measurement of HIV, syphilis, chlamydia, gonorrhoea, and herpes simplex virus type 2 (HSV-2). The analysis will explore factors including alcohol and drug use, social isolation or its polar opposite social support, and peer pressure that may mediate risk behaviour in migrants.

Publications

Issingo R, Voeten H, Urassa M, Kishamawe C, Knoop E, Habemma D, Mwaluko G, Boerma T, Zaba B. Mobility is an important risk factor for HIV infection in rural Tanzania. Paper presented at XIV International AIDS conference, Barcelona, July 2002 abstract no. MoPeC3532

Hélène Voeten, Richard White, Basia Zaba, Simon Gregson, Dik Habbema. Migration as an explanatory factor for differences in HIV prevalence between cities in sub-Saharan Africa. Submitted to Lancet, 2003.

Title	POLICY TRANSFER IN INFECTIOUS DISEASES
Countries	Mozambique and South Africa
LSHTM staff	Gill Walt, Louisiana Lush, Jessica Ogden
Collaborators	Centre for Health Policy, Wits University, Johannesburg, South Africa Universidade Eduardo Mondlane and Ministry of Health, Maputo, Mozambique
Funding	ESRC
Dates	January 2000 – June 2003

Summary

Investigation into development of international policies for infectious diseases with case studies of syndromic management for sexually transmitted infections and DOTS for tuberculosis. Subsequent analysis of transfer of policies to national level in South Africa and Mozambique.

Publications

Lush, L., G. Walt and J. Ogden (2003) Transferring policies for treating sexually transmitted infections: what's wrong with global guidelines?. *Health Policy and Planning* **18**(1): 18-30.

Ogden, J., L. Lush and G. Walt (2003) The politics of branding in public health: the case of DOTS for tuberculosis control. *Social Science and Medicine* **57**(1): 163-172.

Walt, G., L. Lush and J. Ogden (Forthcoming) Policy transfer: iterative loops, adoption, adaptation and marketing in infectious disease. *Governance*

Schneider, H., L. Lush and J. Ogden (2003) *Policy transfer in South Africa: syndromic management for sexually transmitted infections*. Working paper of Johannesburg, Centre for Health Policy, University of the Witwatersrand and London, Health Policy Unit, London School of Hygiene and Tropical Medicine.

Schneider, H., J. Ogden and L. Lush (2003) *Policy transfer in South Africa: DOTS for tuberculosis*. Working paper of Johannesburg, Centre for Health Policy, University of the Witwatersrand and London, Health Policy Unit, London School of Hygiene and Tropical Medicine.

Title	UNAIDS 5-YEAR EVALUATION
Countries	Global
LSHTM staff	Louisiana Lush
Collaborators	ITAD, UK KIT (Royal Tropical Institute) Amsterdam, the Netherlands
Funding	UNAIDS
Dates	September 2001 – September 2002

Summary

Thematic, comparative study of the governance global programmes to learn lessons for UNAIDS' governance and management. Participation in evaluation methodology development and eight country visits.

Publications

Lush, L. (2002) *Evaluation of UNAIDS Thematic Study: Comparative Governance of Global Programmes*. London: Health Policy Unit, London School of Hygiene and Tropical Medicine

Title	ENHANCING ACCESS TO ANTIRETROVIRALS AND OTHER ASPECTS OF HIV/AIDS CARE
Country	Global
LSHTM staff	Louisiana Lush
Collaborators	Royal Institute of International Affairs, London, UK
Funding	DFID

Summary

As part of DFID AIDS/STI programme, analysis of political background to current international debate around enhancing access to drugs with antiretrovirals at the centre. Paper written and conference on access to essential medicines organised jointly with the Royal Institute of International Affairs at Chatham House. Further work underway to investigate the role of private resources in enhancing access, including through public-private partnerships.

Publications

Lush, L. (2001) Editorial. International effort for anti-retrovirals: a storm in a teacup? *Tropical Medicine and International Health* **6**(7): 491-495.

Walt, G. and L. Lush (2001). Getting drugs to the ground: global public private partnerships for neglected diseases. *Biotechnology and Development Monitor* **46**: 9-12.

Lush, L. (2002) International effort for anti-retrovirals: politics or public health? In Granville, B. (ed) Proceedings of conference on the Economics of Essential Medicines. London: Royal Institute of International Affairs.

Lush, L. (Forthcoming) Why do the poor not have access to essential medicines? In Attaran, A. and B. Granville (eds) *Delivering Essential Medicines: the Way Forward*. London: Royal Institute of International Affairs.

5.2 Prioritisation of resources

Title	POLICY AND BEHAVIOURAL RESEARCH: BUILDING RIGHTS BASED APPROACHES TO HIV/AIDS IN PAKISTAN: A NATIONAL CIVIL SOCIETY CAPACITY BUILDING PROJECT
Country	Pakistan
LSHTM staff	Megan Douthwaite, Susannah Mayhew, Shehla Zaidi
Collaborators	Aga Khan University, Karachi, Pakistan
Funding	European Commission through Interact Worldwide
Dates	2004 – 2006

Summary

The overall objective of the project is to make a significant and sustainable contribution to combating the spread of HIV/AIDS in Pakistan, in line with the National HIV/AIDS strategic framework 2001-2006. Within this context staff from the Centre for Population Studies will collaborate with the Aga Khan University to implement 3 research components:

1. Formative research to assess the knowledge, beliefs, attitudes and behaviours associated with risk practices and with health seeking behaviour of suspected high-risk groups;
2. Interventions or operations research;
3. A qualitative analysis of the structural, political and regulatory linkages between the National AIDS Control Programme and the NGO Consortium using in-depth interviews and documentary analysis at various levels.

The study will draw conclusions and make recommendations on the effectiveness of the partnership approach to provide quality care to groups at high-risk of STI/HIV infection.

Title	SOCIO-ECONOMIC IMPACT OF HIV ON HOUSEHOLDS IN NORTHERN MALAWI
Country	Malawi
LSHTM staff	Mia Crampin, Sian Floyd, Judith Glynn, Philip Broadbent, Keith Branson, Paul Fine
Collaborators	<ul style="list-style-type: none"> • Frank Mwaungulu (Karonga Prevention Study Malawi) • John Parry, Dr Jonathan Clewley (PHLS) • Nyovani Madise (Southampton)
Funding	Wellcome Trust

Summary

Objectives

To measure the impact of HIV on individuals and households in Northern Malawi.

Methods

As part of the Karonga Prevention Study in Northern Malawi, filter paper blood samples from general population samples from the 1980s have been HIV tested. These form the basis of a retrospective cohort study. All (197) HIV positive individuals and 396 (initially) HIV negative matched individuals, and their families, were traced in 1998-2000. Possible seroconversion was assessed by tests, verbal autopsies and spouses' status. Interviews included information on children, morbidity and mortality and socio-economic status.

Results

Information was obtained on all but 11 index individuals. 10-year survival was 36% in HIV positives and 93% in (initially) HIV negatives. The age/sex-adjusted hazard ratio for mortality by HIV status, excluding seroconverters, was 15.2 (95% confidence interval 9.8-23.6). Survival time decreased with age, but relative survival, compared to HIV negatives, was similar across age groups. Spouses of initially HIV positive cases had 3.2 times the mortality of spouses of initially HIV negative cases, and survivors were 5.4 times as likely to be HIV positive. Among children with HIV positive mothers, infant mortality was 27% (95% confidence interval 19-38), under 5 mortality 46% (36-58) and under 10 mortality 49% (38-61). The corresponding figures for those with HIV negative mothers were 11% (9-13), 16% (13-19) and 17% (14-20). Twenty-six percent of the wives of HIV-positive index men experienced household dissolution precipitated by widowhood, compared to just 5% of wives of HIV-negative index men, while 30% of surviving wives of HIV-positive index men who were living in the district at the time of follow-up were household heads, compared to just 5% of such wives of HIV-negative index men. Thirty-six percent of children born to an HIV-positive index individual had lived apart from both parents, compared to 12% of children born to an HIV-negative index individual.

Publications

Floyd S, Crampin AC, Glynn JR, Madise N, Mwenebabu M, Mlenga L, Mnkondia S, Ngwira B, Zaba B, Fine PEM. The long-term impact of HIV on household structure in rural Malawi. Abstracts of conference on "Empirical Evidence for the Demographic and Socio-Economic Impacts of HIV/AIDS". Durban, South Africa, 26-28 March 2003.

Crampin AC, Floyd S, Glynn JR, Madise N, Nyondo A, Khondowe MM, Njoka CL, Kanyongoloka H, Ngwira B, Zaba B, Fine PEM. The long-term impact of HIV and orphanhood on the mortality and physical well-being of children in rural Malawi. *AIDS* 2003; 17(3):389-97.

Crampin AC, Floyd S, Glynn JR, Madise N, Nyondo A, Khondowe MM, Njoka CL, Kanyongoloka H, Ngwira B, Zaba B, Fine PEM. The long-term impact of HIV and orphanhood on the mortality and physical well-being of children in rural Malawi. Abstracts of the XIV International AIDS Conference. Barcelona, Spain, 7-12 July 2002.

Crampin AC, Floyd S, Glynn JR, Sibande F, Mulawa D, Nyondo A, Broadbent P, Bliss L, Ngwira B, Fine PEM. Long term follow-up of HIV positive and negative individuals in rural Malawi. *AIDS* 2002;16:1545-60

Crampin AC, Floyd S, Sibande F, Mulawa D, Broadbent P, Bliss L, Ngwira B, Glynn JR, Fine PEM. Long term follow-up of HIV positive and negative natural history cohorts in rural Malawi. Abstract P5.1 XXIV General Population Conference, Salvador-Bahia, Brazil, 18-24 August 2001.

Glynn JR, Pönnighaus J, Crampin AC, Sibande F, Sichali L, Nkhosa P, Broadbent P, Fine PEM. The development of the HIV epidemic in Karonga District, Malawi. *AIDS* 2001;**15**:2025-9.

Title	IS HELMINTH INFESTATION ASSOCIATED WITH AN INCREASED RATE OF PROGRESSION OF HIV DISEASE IN UGANDA?
Country	Uganda
LSHTM staff	Michael Brown, Alison Elliott, James Whitworth
Collaborators	<ul style="list-style-type: none"> • Professor James Whitworth (MRC Programme at Uganda Virus Research Institute) • The AIDS Support Organisation (TASO) Entebbe, Uganda • Professor David Dunne (Molteno Institute, Department of Pathology, University of Cambridge, UK) • Professor Frances Gotch (Department of Immunology, Imperial College School of Medicine, London, UK)
Funding	Wellcome Trust Research Training Fellowship in Clinical Tropical Medicine
Dates	October 2000 – September 2003

Summary

Concurrent infection with HIV and helminths is common in developing countries. The type 1/type 2 model of immune responses to infection would suggest a detrimental effect of helminth infection, as the balance in favour of type 2 cytokines at the expense of type 1 cytokines might encourage HIV progression. It has been suggested that anti-helminthic therapy is an appropriate intervention as part of the package of care for HIV-infected individuals in developing countries; but this has not been subjected to study in an epidemiological setting.

To address these issues, participants in an existing prospective cohort of HIV-infected adults in Uganda were screened for helminth infection using a range of diagnostic parasitological techniques, then mass treated for intestinal nematodes and selectively treated for *Schistosoma mansoni*.

Helminth prevalence, diagnostic issues and risk factors for infection in this context have been studied. The associations between helminth infection, CD4+ T-lymphocyte count and HIV-1 RNA load; to effects of treatment on these outcomes; and the relationships between helminth infection and subsequent mortality rates have been analysed.

Immunological studies of helminth infection in study participants were studied in a whole blood assay of antigen-specific and mitogen-induced cytokine responses, and ELISA for serum cytokines.

Association between helminth infection and HIV progression, or between helminth infection and the immune response, differed according to helminth species.

The results challenge the hypothesis that helminth infection has a detrimental effect on HIV progression.

Title	MICROBICIDES DEVELOPMENT PROGRAMME: ECONOMIC ANALYSIS TO ASSESS DEMAND, COST-EFFECTIVENESS AND INFORM FUTURE DISTRIBUTION STRATEGIES
Country	South Africa, Zambia
LSHTM staff	Fern Terris-Prestholt, Charlotte Watts, Lilani Kumaranayake
Collaborators	Sheena McCormack and Andrew Nunn (MRC clinical trials unit, London) Sinead Delany and Helen Rees (RHRU, Baragwanath Hospital, Johannesburg, South Africa); Gita Ramjee (MRC, Durban, South Africa), Prof Bhat (UTH, Lusaka, Zambia)
Funding body	DFID
Dates	2002 – 2005

Summary

Microbicides are substances capable of reducing the transmission of HIV and other sexually transmitted diseases (STDs) when applied in the vagina. DFID has funded a programme of microbicide development that would provide women with an HIV prevention method they can control. A number of economic considerations will affect future interest in and uptake of microbicides. Economic modelling and analysis will be used to:

- i) estimate the potential demand and market for a microbicide in a couple sub-Saharan African countries;
- ii) assess the cost, accessibility and equity implications of different mechanisms of microbicide distribution;
- iii) empirically assess the cost-effectiveness of the Phase III microbicide trials;
- iv) estimate the cost-effectiveness of interventions promoting microbicide use in the trial countries.

Economic analysis of market supply and demand will be used to develop a framework for assessing the demand, willingness-to-pay for a microbicide. In a number of trial sites behavioural data collected by PSI will be used in combination with demographic, household and economic data to estimate the potential demand and market for a microbicide, and to assess the cost, accessibility and equity implications of different mechanisms of microbicide distribution. This work will build upon ongoing work on the economics of HIV/AIDS, and use available data on the costs of providing HIV prevention and family planning commodities. A full economic costing of the Phase III microbicide trials will be conducted, with a protocol developed using established cost methodologies. The cost data obtained will be used, in combination with the intervention outcome and impact data to consider the aggregate cost-effectiveness of the multi-site trial. In addition, the cost and output data will be used in combination with mathematical models of impact in other epidemiological contexts, to model the potential cost-effectiveness of scaled up interventions in the trial countries. All work will be conducted in collaboration with collaborating country economists.

Progress

Meetings have been held with trial PIs to plan economic studies.

The questions on the case record formed aimed at collecting data on socio-economic status have been reviewed and revised in collaboration with country teams to capture intra-site variation.

Title	COST-EFFECTIVENESS OF BROTHEL-BASED STI TREATMENT FOR SEXWORKERS IN HILLBROW, SOUTH AFRICA
Country	South Africa
LSHTM staff	Peter Vickerman, Fern Terris-Prestholt, Charlotte Watts, Lilani Kumaranayake
Collaborators	Sinead Delany and Helen Rees (RHRU, Baragwanath Hospital, Johannesburg, South Africa)
Funding body	DFID innovations grant HEFP
Dates	2000-2002

Summary

Hillbrow, the inner-city neighbourhood of Johannesburg, South Africa, has high levels of sex-work and a highly mobile population. There is a high prevalence of STI, with surveillance data showing a prevalence of 5.9% and 45.7% for syphilis and HIV respectively, among STD clinic attendees. There is a high turnover rate among the commercial sex-workers (CSWs), with many young women entering the trade. These young women often do not seek prompt STI treatment at government health clinics. Since 2000, the Reproductive Health Research Unit (RHRU) has been implementing a brothel-based STI treatment intervention. This study estimated the cost-effectiveness of this intervention during its first year of activity.

Full annual financial and economic costs were collected using the standardised costing methodology laid out in the Costing Guidelines for HIV Prevention. Costs for the start-up and implementation of the intervention were included, research cost were removed. Behavioural data was collected from sex workers, female family planning clients and male STD clients in Hillbrow, epidemiological and intervention related data was collected from sex workers attending the intervention, other relevant epidemiological data was collected from other populations from the nearby area. The data was used with an epidemiological model, POP 1.0, to project the patterns of HIV and STI transmission among the sex workers and the general population. The model projections were fit to available HIV and STI prevalence data from Hillbrow, and these simulations were used to estimate the number of cervical, GUD and HIV infections averted by the project. The uncertainty in model parameters was used to obtain confidence intervals around the impact estimates.

Results

Total annual cost of the intervention was around \$110,301. The intervention reached 1431 women and provided 2523 visits during this time. Model estimates showed 90 HIV infections averted and 5512 cervical infection averted. Cost per HIV infection averted was around \$1226, and cost per DALY saved was \$46. Although targeted interventions are especially recommended in early HIV epidemics this study shows targeted interventions can still be cost effective in established epidemics.

Publications

Vickerman P, Terris-Prestholt F, Delany S, Watts C, Kumaranayake L. *Modelling the impact and cost-effectiveness of a brothel-based STI treatment intervention for commercial sex workers in Hillbrow, Johannesburg, South Africa*. Report for UK DFID Innovations Grant, 2002.

Conference presentations

Terris-Prestholt F, Delany S, Vickerman P. et al. *Are targeted HIV prevention activities cost-effective in high prevalence settings? Results from Johannesburg, South Africa* IHEA 2003, 4th World Congress, San Francisco, United States, June 2003.

Terris-Prestholt F, Delany S, Vickerman P. et al. *Cost-effectiveness of a brothel-based sexually transmitted infection service among highly mobile sex-workers in Johannesburg, South Africa*. 14th International AIDS Conference, Barcelona, Spain, July 2002.

Title **RESOURCE CENTRE FOR CHINA-UK HIV/AIDS PREVENTION AND CARE (HAPAC) PROJECT**

Country China (Yunnan and Sichuan Provinces)

LSHTM staff Philippe Mayaud, David Mabey, Susan Beckerleg, Lilani Kumaranayake, Fern Terris-Prestholt, Louisiana Lush, Gill Walt, Heiner Grosskurth, Linda Morison

Collaborators

- Cheng Feng, Billy Stewart (China-UK HAPAC project), Beijing, China
- National Centre for AIDS Control, Beijing, China
- National STD Control Centre, Nanjing, China
- Health Bureaus of Yunnan and Sichuan Provinces, China
- Family Health International (FHI), Washington, USA & Bangkok Thailand
- John Richens, Robert Power (Department of STD, University College London Medical School)

Funding DFID through subcontract with FHI

Dates November 2000 – November 2002 (extension through consultancies)

Summary

The project is to provide technical consultancies during the inception phase of a large 5-year DFID bilateral project for HIV/AIDS Prevention and Care (HAPAC) in two provinces of China.

This demonstration project aims to set up best practice interventions for HIV/AIDS and STI prevention and care strategies targeting high-risk groups including commercial sex workers (CSWs), intravenous drug users (IDUs) and men who have sex with men (MSM), through the involvement of target groups and NGOs. The project has four outputs:

- Strengthened strategic planning, management, and implementation capacity in key institutions in order to deliver more effective HIV/AIDS/STI policy and practice;
- High-risk behaviours among primary target populations reduced through implementation of replicable models of HIV/STI prevention and STI treatment;
- Care and support for people living with HIV/AIDS improved;
- Project evaluation and system developed and operationalised.

The multi-disciplinary team of London-based consultants will provide input into:

- Design of a comprehensive Situation Analysis of Sexual health (SASH) in the 2 project Provinces;
- Design of best practice interventions for HIV/AIDS & STI prevention and care targeting high-risk groups (CSW and IDU);
- Design of second generation HIV surveillance systems;
- Design of economics and policy analysis studies;
- Training and study tours.

Main results/outcomes

In the two years of the project, consultants have:

- Facilitated several workshops for the design of SASH and reviewed the initial stages of SASH implementation;
- Prepared best practice documents and strategies for intervention among CSW and IDU;
- Organised a policy study tour in Amsterdam and London;
- Organised a policy training orientation course in London;
- Organised workshops on policy and economic studies.

Publications

China-Uk Project. Situational Analysis in Sexual Health in Two Provinces in the People's Republic of China, 2002. ASH: Final project report.

In preparation

Quality of STI service provision in pharmacies of Sichuan and Yunnan Provinces, China.
An economic analysis of STI services in economics of STI care in China.

Title	IMPLEMENTATION AND EVALUATION OF THE RTI PROGRAMME GUIDANCE TOOL
Countries	Brazil, Cambodia, Ghana and Latvia
LSHTM staff	Sarah Hawkes
Collaborators	<ul style="list-style-type: none"> • Nathalie Broutet, Kevin O'Reilly (WHO) • Johannes van Dam (Horizons) • Lisanne Brown (University of Tulane, New Orleans, USA) • Telma Queiroz, Guida Silva (Brazil) • Hor Bun Leng, Sau Kessana (Cambodia) • Gunta Ladzane (Latvia) • John Gyapong, Placide Tapsoba (Ghana)
Funding	<ul style="list-style-type: none"> • WHO • USAID (through Horizons Programme)
Dates	1998 – present

Summary

The *RTI Programme Guidance Tool (PGT)* is an approach that identifies and addresses the management, technical, socio-cultural, and economic issues that affect the ability of a particular health system to deliver effective interventions. It is an action-oriented process that enables decision makers to set goals and directions, and to prioritise interventions for addressing the problem of Reproductive Tract Infections (RTIs).

The process is based on the experiences of countries implementing the Strategic Approach to Improving the Quality of Care of Reproductive Health Services—a methodology that has been implemented by WHO and its partners in 18 countries to date.

This three-stage approach promotes the concept that appropriate decisions concerning policy and programme development should be based on an understanding of the relationships among clients, the service delivery system, and the mix of services and interventions being provided, while taking into account how these interactions are influenced by the broader socio-cultural and political context. The RTI PGT tool was pilot tested in four counties - Latvia, Ghana, Brazil, and Cambodia - beginning in 1999. An evaluation was carried out in each country in 2002 and early 2003. The evaluation focused on the programmatic outcome of the PGT process and its perceived utility to those involved and affected by the process. The evaluation reported that Government involvement at every step of the process is key. In those cases where the government was not involved the process did not progress very well. However, where the capacity of the government is weak it may not be ideal for them to lead the process. At the beginning of the RTI PGT process it is crucial to identify the capacity of the government and to identify an appropriate role for them that both insures their active involvement, but prevents them from being a barrier to the successful implementation of the process.

Understanding the context within which the RTI PGT process is being implemented is essential. This includes the role of health sector reform, political changes, and economic changes. With a clear understanding of the context, the RTI PGT process can fit into the on-going dynamics in a country and help the process.

The results of the four country evaluations suggest that the RTI PGT process can play an important role in synthesizing the existing information on RTIs in a given country and coordinating all the different groups involved in RTI programming. However, it may be unrealistic in some settings for the PGT.

Publications

- How to use the Programme Guidance Tool: A Brief Guide to the 10 Steps
- A generic funding proposal (example from China) and suggested budget for Stage 1 activities
- Technical papers : What is the Programme Guidance Tool ? Why use it ?; The RTI Programme Tool : Suggestions for Inclusion in a Background Paper ; How to Conduct a Rapid Assessment within the RTI Programme Guidance Tool
- Three country-level background papers : Control of Reproductive tract Infections in Ceará, Brazil : A Background Paper ; also for Ghana and Latvia
- Three Rapid Assessment Reports for Brazil, Ghana, and Latvia
- Three country-level Recommendations : Priority Interventions for Brazil, Ghana, and Latvia
- Three country-level Evaluation Reports for Brazil, Ghana, and Latvia